Public Health England

NHS

Publications approval reference: C1395

Patient Group Direction for Comirnaty® COVID-19 mRNA vaccine

This Patient Group Direction (PGD) is for the administration of Comirnaty® COVID-19 mRNA vaccine to individuals in accordance with the national COVID-19 vaccination programme

This PGD is for the administration of Comirnaty® COVID-19 mRNA vaccine by registered healthcare practitioners identified in Section 3.

The national COVID-19 vaccination programme may also be provided under national protocol or on a patient specific basis (that is by or on the direction of an appropriate independent prescriber). Supply and administration in these instances are not covered by this PGD.

Reference no:	Comirnaty COVID-19 mRNA vaccine PGD
Version no:	v01.00
Valid from:	06 August 2021
Review date:	1 October 2021
Expiry date:	31 March 2022

Public Health England (PHE) has developed this PGD for authorisation by NHS England and NHS Improvement to facilitate the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement and those providing services in accordance with this PGD must not alter, amend or add to the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHS England and NHS Improvement. Section 7 is to be completed by registered practitioners providing the service and their authorising/line manager.

Operation of this PGD is the responsibility of NHS England and NHS Improvement and service providers. The final authorised copy of this PGD should be kept by NHS England and NHS Improvement for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a counter signature, unless there are contractual arrangements for self-declaration.

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE developed COVID-19 vaccine PGDs can be found via: COVID-19 vaccination programme - GOV.UK (www.gov.uk)

The most current national recommendations should be followed. This may mean that a Patient Specific Direction (PSD) is required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD. Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

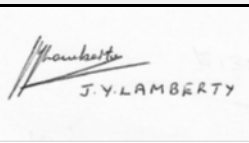
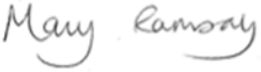
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change history

Version	Change details	Date
V01.00	New PHE PGD template for Comirnaty® COVID-19 mRNA vaccine	06 August 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Jacqueline Lamberty Lead Pharmacist Medicines Management Services, PHE		06/08/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		06/08/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		06/08/2021

In addition to the signatories above the working group included:

Name	Designation
Elizabeth Graham (contributing author)	Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, Public Health England
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHS England and NHS Improvement
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHS England and NHS Improvement
Bhavana Reddy	Director of Pharmacy - Clinical Workstream, Flu and COVID-19 Vaccination Programme, NHS England and NHS Improvement
Gul Root	Principal Pharmaceutical Officer, Department of Health and Social Care and National lead pharmacy public health, Public Health England

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England

Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHS England and NHS Improvement completed below.

NHS England and NHS Improvement accepts governance responsibility for this PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, relevant NHS standard operating procedures (SOPs) and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement authorises this PGD for use by the services or providers delivering the national COVID-19 vaccination programme.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHS England and NHS Improvement	Dr Jonathan Leach OBE		11/08/2021

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation records, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics (SPC) and/or in accordance with official national recommendations.

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • 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. Practitioners must also fulfil all of the Additional requirements.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the SPC, and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant NHS standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and NHS Standard Operating Procedures and in line with the Training recommendations for COVID-19 vaccinators. • must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 as required by national or local policy. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Mental Capacity Act 2005) and to discuss issues related to vaccination

Continued over page

Additional requirements (continued)	• must be competent in the correct handling and storage of vaccines, and management of the cold chain • 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 • must be competent in the intramuscular injection technique • 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 • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and PHE COVID-19 vaccination programme: Information for healthcare practitioners • must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months) or have used the tool for self-assessment if experienced vaccinator (vaccinated within past 12 months) • should fulfil any additional requirements defined by local or national policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis. Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Comirnaty® COVID-19 mRNA vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.

Criteria for inclusion	Comirnaty® COVID-19 mRNA vaccine should be offered, in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance, to:
	• all individuals aged 18 years[2] and over (including those who those who are within three months of their 18th birthday)
	• individuals 16 years to 18 years of age who are:
	  ○ frontline health and social care workers (see Chapter 14a)
	  ○ in an at-risk group (see the table 'Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation' in Chapter 14a)[3] including clinically extremely vulnerable[4] individuals (see Definition of clinically extremely vulnerable groups)
	• other individuals 16 and 17 years of age. **This group is currently only eligible for one dose of the vaccine (**See Dose and frequency of administration)
	• children and those aged 12 years and over with specific underlying health conditions that put them at risk of serious COVID-19
	  ○ At the time of writing JCVI advised that children 12 to 15 years of age with severe neuro-disabilities, Down's syndrome, underlying conditions resulting in immunosuppression, and those with profound and multiple learning disabilities (PMLD), severe learning disabilities or who are on the learning disability register are considered at increased risk for serious COVID-19 disease and should be offered COVID-19 vaccination (see Chapter 14a and latest JCVI statement for current recommendations at: JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 4 August 2021 - GOV.UK (www.gov.uk))
	• those aged 12 years and above 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

[2] JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 15 July 2021 advised that: Operationally, it is considered reasonable to allow a lead-in time to offer vaccination to those children who are within three months of their 18th birthday to ensure good uptake of vaccine in newly-turned 18 year olds.
[3] This also includes adult carers.
[4] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.

Criteria for exclusion[5]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained. The Patient Information Leaflet (PIL) for Comirnaty® COVID-19 mRNA vaccine should be available to inform consent. Individuals who: • are less than 12 years of age • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine or to any component of the Comirnaty® COVID-19 mRNA vaccine or residues from the manufacturing process[6] • have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • have history of idiopathic anaphylaxis • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full dose of COVID-19 vaccine in the preceding 21 days • have completed a course of COVID-19 vaccination Note: individuals aged 16 and 17 years of age who are not frontline health and social care workers, or who are not in an at-risk group are currently eligible for one dose only
Cautions, including any relevant action to be taken Continued over page	All recipients of the Comirnaty® COVID-19 mRNA vaccine should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites. Where individuals experienced a possible allergic reaction to a first dose of COVID-19 vaccine follow the guidance in Chapter 14a of the Green Book in relation to the administration of subsequent doses. 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. 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. Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. Although clinical trials on the use

[5] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

[6] Contains polyethylene glycol (PEG), refer to the SPC for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	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 and Moderna vaccines in the USA with no safety signals so far. Over 50,000 women now report having been vaccinated whilst pregnant or when they might be pregnant in England. Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. Pregnant women who commenced vaccination with COVID-19 Vaccine AstraZeneca, however, are advised to complete the course with the same vaccine. Women who have started a course of COVID-19 Vaccine AstraZeneca, may complete vaccination during pregnancy using COVID-19 Vaccine AstraZeneca. The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see Vaccination (rcog.org.uk)). Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the 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 was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. The individual/carer should be informed about the risk of haematoma from the injection. A very small number of cases of Guillain-Barre Syndrome (GBS) have been reported after Pfizer-BioNTech vaccination, but these reports have not reached the number expected to occur by chance in the immunised population. Individuals who have a history of GBS should be vaccinated with Comirnaty® as recommended for their age and underlying risk status. As there is no evidence to suggest that having had a prior diagnosis of GBS predisposes an individual to further episodes, 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. Based on an understanding of the natural history of GBS, the same vaccine product may be used to complete the course; using an alternative product may increase the chance of experiencing known side effects. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the trial investigators. Eligible individuals who are enrolled in vaccine trials should
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Cautions, including any relevant action to be taken (continued)	then be provided with written advice on whether and when they can be safely vaccinated in the routine programme. **Past history of COVID-19 infection** 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. 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 onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual 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. **Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Administration under this PGD must be in accordance with the most up-to-date advice or amendments (see Green Book Chapter 14a and the SPC). These documents take precedence for the purposes of compliance with this PGD, if there is a delay in updating other provisions of this PGD that cut across them.
Action to be taken if the patient is excluded Continued over page	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient specific basis, under a PSD. For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. Special precautions as described in Chapter 14a, and consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with: • 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 (such as depot steroid injection,

Action to be taken if the patient is excluded (continued)	laxative) • history of idiopathic anaphylaxis Such individuals should not be vaccinated with Comirnaty® COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist and under a PSD. The AstraZeneca COVID-19 vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, the AstraZeneca COVID-19 vaccine should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30-minute observation period is recommended. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	Comirnaty® concentrate for dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) 1 vial (0.45ml) contains 6 doses of 0.3ml after dilution. 1 dose (0.3ml) contains 30micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles). Note: Where appropriate to the delivery model, this PGD may also be used for the administration of vaccine that has been prepared (diluted) by another person in accordance with the manufacturer's instructions and Human Medicines Regulation 3A (UK Statutory Instrument 2020 No. 1594), that is prepared by or under the supervision of a doctor, a registered nurse or a pharmacist.
Legal category	Prescription only medicine (POM).
Black triangle▼	Yes. As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	The Comirnaty® COVID-19 mRNA vaccine SPC recommends the second dose is administered 3 weeks after the first dose. There is evidence of better immune response and/or protection from COVID-19 vaccines where longer intervals between doses are used. Therefore, Comirnaty® COVID-19 mRNA vaccine should be administered under this PGD in accordance with official national recommendations from the JCVI for the delivery of the COVID-19 vaccination programme in England (see Chapter 14a). At the time of writing, JCVI recommends an interval of 8 to 12 weeks between doses. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration Continued over page	Comirnaty® COVID-19 mRNA vaccine is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Comirnaty® COVID-19 mRNA vaccine requires dilution in its original vial with 1.8ml of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3ml dose for administration. Vaccine should be prepared in accordance with manufacturers recommendations (see the product's SPC) and NHS standard operating procedures for the service.

Route / method of administration (continued)	Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use. Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles. The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 0.9% solution for injection, using a 21 gauge or narrower needle and aseptic techniques. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe. Gently invert the diluted dispersion 10 times. Do not shake the vaccine. The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present. The diluted vials should be marked with the appropriate date and time. After dilution store at 2ºC to 30 ºC and use within 6 hours, including any transportation time. Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use. The vaccine dose should be drawn up from the diluted vial immediately prior to administration. In order to extract at least 6 doses from a single vial, low dead-volume syringes and/or needles should be used. Each dose must contain 0.3ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Discard any unused vaccine within 6 hours after dilution. Check product name, batch number and expiry date prior to administration. If the individual has been identified as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes.
Dose and frequency of administration Continued over page	A two-dose course should be administered to all groups except for 16 and 17 year olds who are not frontline health and social care workers, or who are not in an at-risk group (see below). The two-dose course consists of 30micrograms in 0.3ml followed by a second dose of 30micrograms in 0.3ml after an interval of at least 21 days. However, the schedule should usually be administered in accordance with official national guidance which, at the time or

Dose and frequency of administration (continued)	writing, recommends a minimum interval of eight weeks between doses. 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. At the time of writing, 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 this 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 licensed minimal interval of at least 21 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond. If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible, see Additional Information). The course does not need to be restarted. **One dose only should be administered to 16 and 17 year olds who are not frontline health and social care workers, or who are not in an at-risk group.**
Duration of treatment	See Dose and frequency of administration above. Booster doses of COVID-19 vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined.
Quantity to be supplied / administered	Administer 30micrograms in 0.3ml. A two-dose course should be completed, except for 16 and 17 year olds who are not frontline health and social care workers, or who are not in an at-risk group, for whom a one-dose course should be administered.
Supplies	Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Comirnaty® COVID-19 mRNA Vaccine, which ensure use is in accordance with product's SPC and official national recommendations.
Storage Continued over page	Comirnaty® COVID-19 mRNA Vaccine is supplied from the manufacturer as a multiple-dose vial of frozen, preservative-free concentrate, which requires storage at -90°C to -60°C.

Storage (continued)	**Frozen Vial** Shelf life is 6 months at -90°C to -60°C Within the 6 months shelf life, unopened vials may be stored and transported at -25°C to -15°C for a single period of up to 2 weeks and can be returned to -90°C to -60°C. **Thawed vial** Thawed unopened vials have a 1-month shelf-life at 2°C to 8°C. Within the 1-month shelf-life at 2°C to 8°C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30°C. Store in original packaging in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions. Once a vial is removed from the tray, it should be thawed for use. Once thawed the vaccine cannot be re-frozen. **Diluted product** Chemical and physical in-use stability, including during transportation, has been demonstrated for 6 hours at 2ºC to 30ºC after dilution in sodium chloride 0.9% solution for injection. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. **Precautions for storage** Store in original packaging in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions. These details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The product's SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion. 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 off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance.
Disposal Continued over page	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of

Disposal (continued)	safely and securely according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions	The most frequent adverse reactions in individuals 16 years of age and older are injection site pain, fatigue, headache, myalgia, chills, arthralgia, pyrexia and injection site swelling. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Redness at the injection site, nausea and vomiting are reported as common. Lymphadenopathy is reported with a frequency of less than 1%. The most frequent adverse reactions in individuals 12 to 15 years of age are injection site pain, fatigue, headache, myalgia, chills, arthralgia and pyrexia. There have been very rare reports of myocarditis and pericarditis occurring after vaccination with Comirnaty® often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Individuals should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination, which covers the reporting of adverse reactions and their management. Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions Continued over page	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 Coronavirus Yellow Card reporting site

Reporting procedure of adverse reactions (continued)	or search for MHRA Yellow Card in the Google Play or Apple App Store. As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product, see Yellow Card Scheme - MHRA. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.
Written information to be given to patient or carer	Ensure the individual has been provided appropriate written information such as the: • Patient Information Leaflet (PIL) for Comirnaty® COVID-19 mRNA vaccine • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding
Patient advice / follow up treatment	Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see Chapter 14a). Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme on Coronavirus Yellow Card reporting site or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Nationally recommended protective measures should still be followed. When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information Continued over page	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.

Special considerations / additional information (continued)	Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. **Breastfeeding** 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. The developmental and health benefits of breastfeeding should be considered along with the mother'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. Breastfeeding women may be vaccinated under this PGD. **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. Evidence from trials of co-administration suggest that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines 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 the course 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. In these circumstances, this PGD may be used. Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice on completing vaccination in these individuals is available from Public Health England at COVID-19 vaccination: information for healthcare practitioners - GOV.UK (www.gov.uk) **Co-administration with other vaccines** 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 an individual presents requiring two vaccines. It is generally better for vaccination to proceed, and may be provided under this PGD, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. 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 reduce the response to the live virus.

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Special considerations / additional information (continued)	Studies are on-going to support co-administration of COVID-19 vaccines with influenza in the 2021-2022 season. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated Emerging evidence suggests many individuals with immunosuppression are protected after two doses of vaccination. Despite the overall reassuring evidence, some individuals with more severe immunosuppression do not make a good immune response to a complete course of vaccine and may therefore remain at high risk. Post-vaccination testing for spike antibody may be considered by specialists managing individuals with severe immunosuppression. Individuals can then be advised whether to take precautions to reduce their chance of exposure, taking into account their underlying immune defect and any test results. Individuals who have received a bone marrow transplant after COVID-19 vaccination should be considered for re-immunisation. Booster doses and re-immunisation are not currently covered by the national programme and specialists wishing to provide re-immunisation or a booster dose must do so under a Patient Specific Direction (PSD).
Records Continued over page	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be

Records (continued)	in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

6. Key references

Key references	Comirnaty® COVID-19 mRNA vaccine
	• Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 30 July 2021. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics and Patient Information Leaflet for Comirnaty® COVID-19 mRNA vaccine July 2021 https://www.medicines.org.uk/emc/product/12740 • COVID-19 vaccination programme. Updated 6 August 2021. https://www.gov.uk/government/collections/covid-19-vaccination-programme • JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 15 July 2021 https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement/jvci-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-15-july-2021 • JCVI statement: COVID-19 vaccination of children and young people aged 12 to 17 years 4 August 2021 https://www.gov.uk/government/publications/jcvi-statement-august-2021-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years/jcvi-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-4-august-2021 • Guidance on protecting people who are clinically extremely vulnerable from COVID-19: 28 July 2021 https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev • Training recommendations for COVID-19 vaccinators. Published 08 December 2020. https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 16 March 2021 https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 6 August 2021. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

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Key references (continued)	**General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made • UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made

7. Practitioner authorisation sheet

Comirnaty® COVID-19 mRNA vaccine PGD v01.00 Valid from: 6/08/2021 Expiry: 31/03/2022

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

PGDs do not remove inherent professional obligations or accountability.

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

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

Authorising manager

I confirm that the registered healthcare professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

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 PGD.