UK Health Security Agency

NHS

Publications approval reference: C1554

Patient Group Direction for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine

This Patient Group Direction (PGD) is for the administration of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine to children aged 5 to 11 years[1] in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of Comirnaty® 10 micrograms/dose 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® 10 micrograms/dose COVID-19 mRNA vaccine PGD
Version no:	v01.00
Valid from:	20 January 2022
Expiry date:	31 March 2022

The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England and NHS Improvement (NHSEI) to facilitate the delivery of the national COVID-19 vaccination programme.

NHSEI 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)[2] Schedule 16 Part 2, on behalf of NHSEI. 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 NHSEI and service providers. The final authorised copy of this PGD should be kept by NHSEI 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 UKHSA developed COVID-19 vaccine PGDs can be found via: COVID-19 vaccination programme

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] Those aged 12 years, who commence a course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine under 12 years of age, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.

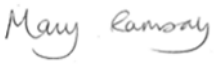
[2] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change history

Version	Change details	Date
V01.00	New UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine	16/01/2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Beth Graham Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		18/01/2022
Doctor (Acting Chair of Expert Panel)	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		18/01/2022
Registered Nurse	Kelly Stoker Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		18/01/2022

In addition to the signatories above the working group included:

Name	Designation
Suki Hunjunt	Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHSEI
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHSEI
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSEI
Gul Root	Principal Pharmaceutical Officer, Department of Health and Social Care and National lead pharmacy public health, Office for Health Improvement and Disparities
Naveen Dosanjh	Senior Clinical Advisor, Clinical Workstream, COVID-19 Vaccination Programme, NHSEI

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel (see below) in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group and the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSEI South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHSEI completed below.

NHSEI 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.

NHSEI 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, NHSEI	Dr Jonathan Leach OBE		20/01/2022

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 SOPs 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 and 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 and to discuss issues related to vaccination. For further information on consent see Chapter 2 of 'The Green Book'. • 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

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Additional requirements (continued)	• must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and 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 the UKHSA and/or NHSEI 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® 10 micrograms/dose COVID-19 mRNA vaccine is indicated for the active immunisation of children aged 5 to 11 years[3] 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' (hereafter referred to as Chapter 14a), and subsequent correspondence/publications from the UKHSA and/or NHSEI.
Criteria for inclusion	Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine should be offered to children aged 5 to 11 years[3] in accordance with the recommendations in Chapter 14a. At the time of writing, this includes: • children aged 5 to 11 years in a clinical risk group (as defined in Chapter 14a) • children aged 5 to 11 years who are a household contact of someone who is immunosuppressed (as defined in the Chapter 14a) • children aged 12 years, who commenced but did not complete a primary course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine
Criteria for exclusion[4]	Individuals for whom valid consent has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient Information Leaflet (PIL) for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine should be available to inform consent. Individuals who: • are less than 5 years of age • are aged 12 years and over, unless 12 years of age and completing a primary course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine commenced at 5 to 11 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 or residue from the manufacturing process[5] in the Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine • have a history of prior allergic reaction to COVID-19 vaccine that required medical intervention in hospital • 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 • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe 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

[3] Those aged 12 years, who commence a course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine under 12 years of age, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.

[4] 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.

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

Cautions, including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and 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. Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5 of the Green Book. No specific management is required for individuals with a family history of allergies. Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in Chapter 14a in relation to the administration of subsequent doses. Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. Syncope (fainting) can occur following, or even before, any vaccination 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. 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/parent/carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). 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

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Cautions, including any relevant action to be taken (continued)	dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after the vaccine (British Society for Haematology-COVID-19). **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 but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, vaccination of high risk children 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. This interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). The timing of any change will be advised by JCVI or UKHSA and published in operational guidance agreed by DHSC and NHSEI. Current advice in Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) cases suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at risk of infection and/or who are fully recovered. 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, the Medicines and Healthcare products Regulatory Agency (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 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

Action to be taken if the patient is excluded (Continued)	possibility of undiagnosed PEG-allergy, is required for individuals with: • history of prior allergic reaction to COVID-19 vaccine that required medical intervention in hospital • 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, laxative) • history of idiopathic anaphylaxis Such individuals should not be vaccinated with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist and under a PSD. Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. 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. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/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® 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) This is a multidose vial and must be diluted before use. One vial (1.3ml) contains 10 doses of 0.2ml after dilution. One dose (0.2ml) contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles). This product in supplied in vials with an orange plastic cap. 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 Continued over page	**Primary immunisation** The Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine SPC recommends the second dose is administered 3 weeks (21 days) 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® 10 micrograms/dose COVID-19 mRNA vaccine should be administered under this PGD in accordance with recommendations from the JCVI and Chapter 14a for the delivery of the COVID-19 vaccination programme in England (see Dose and frequency of administration section). The Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is licensed for those 5 to 11 years of age. This PGD may be used for children 12 years old who are completing a course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in line with advice in Chapter 14a. **Allergy** The Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine SPC recommends close observation for at least 15 minutes 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 (CMO) have recommended suspension of this requirement. This is a temporary suspension in individuals without a history of allergy. However, the individual/parent/carer should be informed about the signs and symptoms of anaphylaxis and 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. In individuals with a personal history of allergy, they should be managed in line with Chapter 14a, Table 5 of the Green Book. No specific management is required for individuals with a family history of allergies. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged.

Off-label use (continued)	**Storage** 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 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/parent/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® 10 micrograms/dose COVID-19 mRNA vaccine is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. This product in supplied in vials with an orange plastic cap. Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine requires dilution in its original vial with 1.3ml of sodium chloride 9mg/ml (0.9%) solution for injection, prior to withdrawing a 0.2ml dose for administration. Vaccine should be prepared in accordance with manufacturer's recommendations (see the product's SPC) and NHS standard operating procedures for the service. **Dose verification of Comirnaty 10 micrograms/dose concentrate for dispersion for injection (children 5 to 11 years)** Verify that the vial has an orange plastic cap. If the vial has a purple plastic cap or a grey plastic cap, it is a Comirnaty 30micrograms/dose product and must not be administered under this PGD. **Handling prior to use** Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 10-vial pack may take 4 hours to thaw. Alternatively, individual frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use. Ensure vials are completely thawed prior to use. **Mixing prior to dilution** 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 1.3ml sodium chloride 9mg/ml (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic technique. Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3ml 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 30ºC and use within 12 hours. Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Route / method of administration (continued)	**Preparation of individual 0.2ml doses** The vaccine dose should be drawn up from the diluted vial immediately prior to administration. Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab. Withdraw 0.2ml of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine. In order to extract at least 10 doses from a single vial, low dead-volume syringes and/or needles should be used. Each dose must contain 0.2ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Discard any unused vaccine within 12 hours after dilution. Check product name, batch number and expiry date prior to administration.
Dose and frequency of administration	A dose of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is 0.2ml and contains 10micrograms of COVID-19 mRNA vaccine in 0.2ml. The two-dose primary course consists of 10micrograms in 0.2ml followed, after an interval of at least 21 days, by a second dose of 10 micrograms in 0.2ml. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which is set out in Chapter 14a and summarised below and in a table at Appendix A. For both adenovirus vector 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 for adults and for children in a risk group. Operationally, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking and will help to ensure a good balance between achieving rapid and long-lasting protection. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the 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. **Interval post SARS-CoV-2 infection** For individuals who have had proven SARS-CoV-2 infection (see Cautions), any subsequent COVID-19 vaccination should ideally be deferred until at least four weeks from onset of symptoms (or sample date) for individuals in risk groups, including contacts of the immunosuppressed. These intervals post SARS-CoV-2 infection may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). The timing of any change will be advised by JCVI or UKHSA and published in operational guidance agreed by DHSC and NHSEI. **Primary course for children at higher risk** The primary course for individuals at higher risk is recommended to be scheduled as follows:

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Dose and frequency of administration (continued)	• individuals aged 5 to 11 years[3] aboveand sharing living accommodation with an immunosuppressed individual of any age should receive a two-dose primary course at a recommended 8-week minimum interval • individuals aged 5 to 11 years[3] and in an at-risk group[6] should receive a two-dose primary course at a recommended 8-week minimum interval. • individuals aged 5 to 11 years[3] who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule should receive a three-dose primary course at a recommended 8-week minimum interval (see 'Box 2: Criteria for a third primary dose of COVID-19 vaccine' in Chapter 14a for eligibility and Additional Information section regarding timing). Those aged 12 years, who commence a course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine under 12 years of age, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a. **Booster vaccination** A decision on boosting in those aged under 12 years is still under consideration and is not covered by this PGD. Those individuals in a risk group who turn 12 years of age will be eligible for a booster a minimum of three months after completion of the primary course, see Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine PGD.
Duration of treatment	See Dose and frequency of administration above.
Quantity to be supplied / administered	Administer 10micrograms in 0.2ml per dose.
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® 10 micrograms/dose COVID-19 mRNA Vaccine, which ensure use is in accordance with product's SPC and official national recommendations.
Storage Continued over page	Comirnaty® 10 micrograms/dose 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. **Frozen Vial** Shelf life is 6 months at -90°C to -60°C The vaccine may be received frozen at -90°C to -60°C or at -25°C to -15°C. Frozen vaccine can be stored either at -90°C to -60°C or 2°C to 8°C upon receipt. **Thawed vial** Up to 10 weeks storage and transportation at 2°C to 8°C within the 6-month shelf life. Upon moving the vaccine to 2°C to 8°C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out.

[6] At risk groups are listed in the Green Book Chapter 14a Table 4

Storage (continued)	If the vaccine is received at 2°C to 8°C it should be stored at 2°C to 8°C. The expiry date on the outer carton should have been updated to reflect the refrigerated expiry date and the original expiry date should have been crossed out. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8°C and 30°C. Thawed vials can be handled in room light conditions. Once thawed the vaccine should not be re-frozen. **Diluted product** Chemical and physical in-use stability, has been demonstrated for 12 hours at 2ºC to 30ºC after dilution in sodium chloride 9mg/ml (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. If not used immediately, in-use storage times and conditions are the responsibility of the user. **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 Vaccine Incident Guidance.
Disposal	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 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 Continued over page	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. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination.

Drug interactions (continued)	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 children 5 to 11 years of age are injection site pain, fatigue, headache, injection site redness and swelling, myalgia and chills. Very rare cases of myocarditis and pericarditis have been observed following COVID-19 vaccination. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Individuals/parents/carers should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. Individuals/parents/carers should be provided with the advice within the leaflet What to expect after your child's COVID-19 vaccination, which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. The individual/parent/carer 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 across all age groups is available in the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme 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. 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/parent/carer has been provided appropriate written information such as the: • Patient Information Leaflet (PIL) for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine • COVID-19 Vaccination Record Card • What to expect after your child's COVID-19 vaccination • A guide for parents of children aged 5 to 11 years of age at high risk • Waiting after COVID-19 vaccination
Patient advice / follow up treatment Continued over page	There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre

Patient advice / follow up treatment (continued)	• informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see leaflets What to expect after your child's COVID-19 vaccination and Waiting after COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5 of the Green Book. Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. The individual/parent/carer should be advised to seek immediate medical attention should the vaccinated child experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/parent/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 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. The individual/parent/carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine. Nationally recommended protective measures should still be followed. When applicable, advise the individual/parent/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. 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. Ideally consent of someone with parental responsibility should be sought, children can self-consent only if assessed as Gillick competent (see Chapter 2 of the Green Book). **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the earlier doses should not be repeated. Those aged 12 years, who commence a course when under 12 years of age of Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.. Individuals who have received a fractional 10microgram dose of the Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine, on a patient specific basis, may complete the course with Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine. Individuals with a history of capillary leak syndrome should be carefully counselled about the risks and benefits of vaccination. Children who have been vaccinated abroad are likely to have received an mRNA vaccine based on the spike protein, or an inactivated whole viral

Special considerations / additional information (continued)	vaccine. If this is the case, Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine may be used to complete a primary course. **Co-administration with other vaccines** Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, 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 or more vaccines. It is generally better for vaccination to proceed and it 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. 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). 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, the individual/parent/carer 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. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 2: Criteria for a third primary dose of COVID-19 vaccine' in Chapter 14a). Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). This is not covered by this PGD/Protocol and should be provided on a patient specific basis.
Records Continued over page	Record: • that valid informed consent was given • 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

Records (continued)	• 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 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® 10 micrograms/dose COVID-19 mRNA vaccine** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 12 January 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics and Patient Information Leaflet for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine. 4 January 2022 https://www.medicines.org.uk/emc/product/13134/smpc • COVID-19 vaccination programme. Updated 10 January 2022. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 4 October 2021. 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 **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • 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® 10 micrograms/dose COVID-19 mRNA vaccine PGD v01.00
Valid from: 20/01/2022 Expiry: 31/03/2022

By signing this Patient Group Direction (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.

APPENDIX A (Read in conjunction with Dose and frequency of administration section)

Recommended primary dose schedule by age and risk status.

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine Primary course for children at higher risk			
Age	**Doses**	**Advised Minimum Interval[7]**	**Recommendations**
5 to 11 years[8] of age and sharing living accommodation with an immunosuppressed individual of any age	Two	8 weeks	Those aged 12 years, who commence a course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine under 12 years of age, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a
5 to 11 years of age[8] in an at-risk group[9]	Two	8 weeks	
5 to 11 years of age[8] and had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule	Three	8 weeks	

[7] For individuals who have had proven SARS-CoV-2 infection (see Cautions), any subsequent COVID-19 vaccination should ideally be deferred until at least four weeks from onset (or sample date) for individuals in a risk group. This interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant).The timing of any change will be advised by JCVI or UKHSA and published in operational guidance agreed by DHSC and NHSEI.

[8] Those aged 12 years, who commence a primary course of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine under 12 years of age, may be vaccinated under this PGD to complete their primary course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.

[9] At risk groups are listed in the Green Book Chapter 14a Table 4 for children.