UK Health Security Agency

NHS England

Publications approval reference: C1701

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 and some children aged 12 years 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:	v5.00
Valid from:	13 December 2022
Review date:	14 June 2023
Expiry date:	14 December 2023

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

NHSE 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 NHSE. 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 NHSE and service providers. The final authorised copy of this PGD should be kept by NHSE 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 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 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@ukhsa.gov.uk

[1] This includes any relevant amendments to legislation

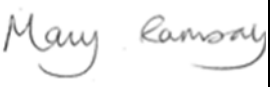
Change history

Version	Change details	Date
V01.00	New UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine	16 January 2022
V02.00	UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine updated, in accordance with the Green Book Chapter 14a 28 February 2022, to: • include all children 5 to 11 years of age (one-off programme) • include individuals aged 12 years and under in school year 7 • move some exclusions pertaining to allergy to cautions section, as special precautions, to allow for administration on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously and similarly update the actions if excluded section • reflect the revised recommendations for those with a past history of COVID-19 infection • clarify the vaccine that can be used to complete the course in the case of incomplete immunisation • update frozen product shelf life from 6 months to 9 months and remove reference to -25 °C to -15 °C storage conditions in accordance with updated summary of product characteristics • update to most sections of the PGD to address the above points and for minor typographical amendment	17 March 2022
V03.00	UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine V02.00 updated, in accordance with the Green Book Chapter 14a 17 August 2022: • to include children aged 5 years to 11 years who are eligible to be offered a COVID-19 booster vaccine in the autumn of 2022 namely those: o in a clinical risk group, as set out in Tables 3 and 4 of the Green Book Chapter 14a o who are household contacts of people with immunosuppression, as defined in Tables 3 and 4 of the Green Book Chapter 14a • off-label section updated to indicate the booster dose is off-label use • updated wording relating to the temporary suspension of the 15-minute wait after administration • updated expiry date under storage from 9 to 12 months at -90°C to -60°C • updated wording in line with standard UKHSA PGD wording	5 September 2022
V04.00	UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine V03.00 updated, in accordance with the Green Book Chapter 14a 4 September 2022: • added those who are eligible to be offered a COVID-19 booster vaccine in the autumn of 2022 (in a clinical risk group or who are household contacts of people with immunosuppression) includes children aged 12 years in school year 7 and added to off-label use • removed reference to Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine PGD under booster immunisation • amended wording under inclusion criteria and previous incomplete vaccination for clarity • updated adverse reactions • updated references NOTE: Final approved and ratified version 4.00 was not published due to a concurrent, significant changes in the SPC	11 October 2022

V5.00	UKHSA PGD for Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine V04.00 updated, in accordance with Summary of Product Characteristics (SPC) dated November 2022 and Green Book Chapter 14a 4 September 2022: • included colour of cap associated with the correct multidose vial in the description of the product • updated the booster information in the off label section • updated the dose and frequency with the timing of the booster and doses for children turning 5 years in Autumn 2022 in risk group • updated adverse reactions • updated supplies section • updated references • updated the table with booster dose	30 November 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)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		01 December 2022
Doctor	Mary Ramsay Consultant Epidemiologist Immunisation and Vaccine Preventable Diseases Division, UKHSA		01 December 2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		01 December 2022

In addition to the signatories above, the working group included:

Name	Designation
Jacqueline Lamberty	Lead pharmacist Medicines Governance Health Equity and Clinical Governance Directorate, UKHSA
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHSE
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHSE
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSE
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, NHSE

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel (see overpage) in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by 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, NHSE
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 Clinical Commissioning Group
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Tushar Shah	Lead Pharmacy Advisor, NHSE London

2. Organisational authorisation

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

NHSE 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.

NHSE 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**
Joint Medical Director, National COVID-19 Vaccination Programme, NHSE	Dr Peter Greengross FFPH FRCS		01 December 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 which 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

Continued over page

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 NHSE 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 and some children aged 12 years 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 'Green Book' (hereafter referred to as Chapter 14a), and subsequent correspondence/publications from the UKHSA and/or NHSE.
Criteria for inclusion	Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine should be offered to children aged 5 to 11 years and some children aged 12 years in accordance with the recommendations in Chapter 14a. At the time of writing, this includes: • all children aged 5 years on or before 31 August 2022 to 11 years and includes children aged 12 years in school year 7 not in a clinical risk group (one-off programme, see Dose and frequency of administration) • children aged 5 to 11 years and includes children aged 12 years in school year 7 in a clinical risk group (as defined in Chapter 14a). • children aged 5 to 11 years and includes children aged 12 years in school year 7 who are a household contact of someone who is immunosuppressed (as defined in 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[2]	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 • turn 5 years of age after 31 August 2022, unless in a risk group or a household contact of someone who is immunosuppressed • are aged 12 years and over, unless 12 years of age and in school year 7 or completing a primary course of Comirnaty® 10 micrograms/dose • 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[3] in the Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine • 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
Cautions, including any relevant action to be taken Continued over page	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 for children without a history of allergy (see allergy

[2] 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.
[3] Contains polyethylene glycol (PEG), refer to the SPC for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	in 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. Special precautions are advised for individuals with a personal history of allergy including a: • prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (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 Individuals with undiagnosed polyethylene glycol (PEG) allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Such individuals should not be vaccinated with the Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously. 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. No specific management is required for individuals with a family history of allergies. 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 (23 gauge or 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

Continued over page

Cautions, including any relevant action to be taken (continued)	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 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 to 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 or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. For children in a risk group, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis, as clinical deterioration can occur up to 2 weeks after infection. For children who are not in a risk group, vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). These recommended intervals after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the Joint Committee on Vaccination and Immunisation (JCVI) or UKHSA and published in NHSE operational guidance. Current advice in Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) suggests an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested, unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. 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.
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 an individual may have, as well as the risk of serious

Action to be taken if the patient is excluded (continued)	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 and vaccination may be provided by an appropriate prescriber or on a patient specific basis, 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 with an orange cap 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) 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 (inserted by 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, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	**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 in the primary schedule 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 children 5 to 11 years of age. Those aged 12 years may also be vaccinated under this PGD to commence or complete a course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a. **Booster immunisation** The Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is licensed for booster doses in individuals aged 5 years to 11 years only. However, individuals aged 12 years in school year 7, who are eligible to be offered a COVID-19 booster vaccine can be given a booster dose in accordance with the JCVI recommendations and Chapter 14a. The SPC states that the booster dose of Comirnaty® 10 micrograms is given 6 months after the primary course. However, the booster dose can be given at a minimum period of 3 months after the final dose of the primary course in accordance with the Green Book 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) recommended a temporary suspension of this requirement. This temporary suspension in children aged 5 to11 years without a history of allergy has also been agreed by the Commission on Human Medicines and remains in place;

Continued over page

Off-label use (continued)	this will be reviewed on a regular basis. 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. 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. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged. **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. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by appropriate data and NHS operational guidance or standard operating procedure. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route and 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** 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® 30 micrograms/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.

Route and method of administration (continued)	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 clearly with the date and time of first use (Chapter 4). The expiry is 12 hours from the point of dilution, but the vial should still be used as soon as practically possible. Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use. **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 10 micrograms of COVID-19 mRNA vaccine in 0.2ml. The 2-dose primary course consists of 10 micrograms 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 8 weeks between doses of all the available COVID-19 vaccines where a 2-dose primary schedule is used for adults and for children in a risk group. Operationally, using the same minimum interval for all products will simplify supply and booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. For children who are not in a risk group a 12-week interval is preferred. This is based on precautionary advice from the JCVI based on emerging evidence of a

Continued over page

Dose and frequency of administration (continued)	lower rate of myocarditis in countries that use schedules of 8 to 12 weeks. The intervals may be shortened to 8 weeks when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval between doses will be advised by JCVI or UKHSA and published in NHSE operational guidance. The main exception to the 8-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 the primary course is interrupted or delayed, it should be resumed (using the same vaccine as was given for the first dose if possible (see Additional Information), but doses should not be repeated. **Interval post COVID-19 infection** For children in a risk group, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen, to avoid confusing the differential diagnosis. For children who are not in a risk group, vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). These recommended intervals after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSE operational guidance. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. **Primary course for children who are not in a risk group** In February 2022 the JCVI advised a one-off, non-urgent programme to offer vaccination to all children aged 5 to 11 years and includes children aged 12 years in school year 7 who were not in a clinical risk group. This one-off programme still applies to children who turned five years of age by 31 August 2022. Where vaccination is offered in school year 7, Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is advised for commencing (and for completing) vaccination. The primary course for individuals who are not in a risk group is recommended to be scheduled as follows: • a 2-dose primary course with a recommended 12-week minimum interval between doses. **Primary course for children in a risk group** The primary course for individuals at higher risk is recommended to be scheduled as follows: • individuals aged 5 to 11 years[Error! Bookmark not defined.] includes children aged 12 years in school year 7, and sharing living accommodation with an immunosuppressed individual of any age should receive a 2-dose primary course at a recommended 8-week minimum interval

Continued over page

Dose and frequency of administration (continued)	• individuals aged 5 to 11 years, Error! Bookmark not defined. includes children aged 12 years in school year 7, and in an at-risk group should receive a 2-dose primary course at a recommended 8-week minimum interval. • individuals aged 5 to 11 years Error! Bookmark not defined. ,includes children aged 12 years in school year 7, who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule should receive a 3-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). **Booster immunisation** Children in risk groups (Chapter 14a Tables 3 and 4) who turn five years of age after August 2022 will become eligible for primary vaccination and can also receive a booster during the autumn programme, provided there is at least three months interval since their second (or third) primary dose. Children aged 5 years to 11 years, and those aged 12 years in school year 7, who are eligible to be offered a COVID-19 booster vaccine in the autumn of 2022, which includes those in a clinical risk group or who are household contacts of people with immunosuppression (as set out in Tables 3 and 4 of Chapter 14a) should receive a 0.2ml dose of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine. Booster in children who are not at risk are not currently recommended by JCVI.
Duration of treatment	See Dose and frequency of administration above.
Quantity to be supplied and administered	Administer 10 micrograms in 0.2ml per dose.
Supplies	COVID-19 vaccines for those authorised by the NHS to deliver the programme will be made available for ordering on the ImmForm website: https://portal.immform.phe.gov.uk/, telephone 0207 183 8580 or through the Foundry ordering platform in England. 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	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 12 months at -90°C to -60°C.The vaccine may be received frozen at -90°C to -60°C. Frozen vaccine can be stored either at -90°C to -60°C or 2°C to 8°C upon receipt. When stored frozen at -90°C to -60°C, 10-vial packs of the vaccine can be thawed at 2°C to 8°C for 4 hours or individual vials can be thawed at room temperature (up to 30°C) for 30 minutes. **Thawed vial** Up to 10 weeks storage and transportation at 2°C to 8°C within the 12-month shelf life. Upon moving the vaccine to 2°C to 8°C storage, the updated expiry date must be written or labelled 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 or labelled over.

Continued over page **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 printed manufacturer's expiry date should have been crossed out or labelled over. 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 as soon as practically possible. 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	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 exist, 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.
Continued over page	

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 are injection site pain, redness (very common in children 5-11 years) or swelling, fatigue, headache, fever, arthralgia, myalgia, chills, diarrhoea, nausea and vomiting. A higher rate of fever was observed after the second dose compared to the first dose. A higher frequency of lymphadenopathy was observed in individuals 5 to 11 years of age in Study 3 (2.5% vs. 0.9%) receiving a booster dose compared to participants receiving 2 doses. Very rare cases of myocarditis and pericarditis have been observed following COVID-19 vaccination. Data indicates that the risk of myocarditis and pericarditis after vaccination with Comirnaty® in children aged 5 to 11 years seems lower than in ages 12 to 17 years. 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. 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, the 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 • A guide for parents of children aged 5 to 11 years of age at high risk • Waiting after COVID-19 vaccination

Patient advice and follow up treatment	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 (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 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. When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations and 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, if possible, but the earlier doses should not be repeated. Children aged 5-12 years who have commenced immunisation with the Comirnaty® 10 micrograms dose should complete vaccination with the 10 micrograms dose. Individuals aged 12 years of age who have commenced immunisation with the Comirnaty® 10 micrograms dose, can be given Comirnaty® 30 micrograms

Special considerations and additional information (continued)	dose to complete vaccination if Comirnaty® 10 micrograms dose is not available. Individuals aged 13 years and above should be given Comirnaty® 30 micrograms dose vaccine to complete vaccination, see Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine PGD. Children aged 12 years who have commenced vaccination with the 30 microgram dose and who are being vaccinated alongside their peers from school year 7 may complete the course with the 10 microgram dose. Individuals who have received a fractional 10 microgram dose of the Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine may complete the course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine using this PGD or vice versa. Administration of a fractional 10 microgram dose of the Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine would be on a patient specific basis only and is not covered by this PGD. Children who have been vaccinated abroad are likely to have received an mRNA vaccine based on the spike protein, or an inactivated whole viral vaccine. If this is the case, Comirnaty® 10 micrograms/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 2 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 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 2 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 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 2 weeks after the second dose of vaccination do not require an additional primary vaccination at this stage, although specialist advice may need to be sought. Children who had received brief immunosuppression (≤2mg/kg prednisolone per day) for an acute episode of asthma and children on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. 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 2 weeks after the period of immunosuppression, in addition to the time period for clearance of

Continued over page

Special considerations and additional information (continued)	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 and should be provided on a patient specific basis.
Records	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 • details of any adverse drug reactions and actions taken • administered 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 4 September 2022 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. November 2022 Comirnaty 10 micrograms/dose concentrate for dispersion for injection Children 5 to 11 years COVID-19 mRNA Vaccine SmPC • Joint Committee on Vaccination and Immunisation (JCVI) updated statement on the COVID-19 vaccination programme for autumn 2022 Published 15 July 2022 www.gov.uk/government/publications/jcvi-updated-statement-on-the-covid-19-vaccination-programme-for-autumn-2022/joint-committee-on-vaccination-and-immunisation-jcvi-updated-statement-on-the-covid-19-vaccination-programme-for-autumn-2022 • COVID-19 vaccination programme. Updated 22 September2022 www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 20 October 2022. www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 20 October 2022 www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 October 2022. www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Preparation of 0.2mL syringes using Comirnaty 10 Concentrate for Children 5–11-year SOP PCV2 V1.00 dated 18 August 2022 www.sps.nhs.uk/articles/preparing-comirnaty-10-concentrate-vaccine/ **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 NHS England » (HTM 07-01) Management and disposal of healthcare waste • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. 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 The Human Medicines Regulations 2012 (legislation.gov.uk) • Regulation 274A, UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

Continued over page

Key references (continued)	The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (legislation.gov.uk) • UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus) (Amendment) Regulations 2020 The Human Medicines (Coronavirus) (Further Amendments) Regulations 2020 (legislation.gov.uk) • UK Statutory Instruments2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (legislation.gov.uk)

7. Practitioner authorisation sheet

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine PGD v05.00
Valid from: 13 December 2022 Expiry: 14 December 2023

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 and booster schedule by age and risk status.

Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine: Primary course for children who are not in a risk group			
Age	**Doses**	**Advised Minimum Interval[4]**	**Recommendations**
5 years to 11 years (one-off programme, not in clinical risk group nor sharing living accommodation with an immunosuppressed individual of any age	2	12 weeks	This one-off programme applies to those currently aged 5 to11 years, and children will continue to become eligible as they turn five years of age until the end of August 2022. JCVI currently has not recommended booster dose for children who are not in a risk group
12 years and under, in school year 7	2	12 weeks	
Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine: Primary course for children in a risk group			
Age	**Doses**	**Advised Minimum Interval[5]**	**Recommendations**
5 to 11 years of age and sharing living accommodation with an immunosuppressed individual of any age	2	8 weeks	This group includes children aged 12 years in school year 7 Those aged 12 years may also be vaccinated under this PGD to commence or complete a course with Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine in accordance with the recommendations in Chapter 14a.
5 to 11 years of age in an at-risk group	2	8 weeks	
5 to 11 years of age and had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule	3	8 weeks	
Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine Booster dose for children in a risk group in the autumn 2022 programme			
5 to 11 years of age and sharing living accommodation with an immunosuppressed individual of any age	1 booster	3months from final primary dose	This group includes children aged 12 years in school year 7
5 to 11 years of age in an at-risk group	1 booster	3months from final primary dose	This group includes children aged 12 years in school year 7

[4] For children who are not in a risk group, vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). This recommended interval after COVID infection may be reduced to ensure operational flexibility when rapid protection is required. Any reduction in the recommended interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSEI operational guidance. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.

[5] For children in a risk group, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen. This recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required. Any reduction in the recommended interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSE operational guidance. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.