UK Health Security Agency

NHS England

Publications approval reference: PRN00855

COVID-19 mRNA vaccine (5 to 17 years of age) Patient Group Direction

This Patient Group Direction (PGD) is for the administration of COVID-19 mRNA vaccine to children and young people aged 5 to 17 years in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of 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:	COVID-19 mRNA vaccine PGD (5 to 17 years of age)
Version no:	v3.00
Valid from:	6 October 2023
Expiry date:	1 April 2024

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[1] (HMR2012) Schedule 16 Part 2, on behalf of NHSE. Section 7 is to be completed by registered practitioners providing the service and their authorising 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 countersignature 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
v1.00	New UKHSA combined PGD to support delivery of the COVID-19 vaccination programme to eligible children and young people aged 5 to 17 years of age.	31 March 2023
V2.00	UKHSA COVID-19 PGD for children and young people (aged 5 to 17 years) updated to: • define individuals in scope for the Autumn 2023 seasonal booster campaign • include vaccines in scope as recommended for each age group • include dose, handling, administration and storage details for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection and Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) dispersion for injection • include a recommended interval of 3 months between doses • recommend a minimum 3 week interval between doses for all vaccines, in individuals receiving planned immunosuppressive treatment (changed from minimum interval recommended in the product SPC); clarity on use of a PSD in this cohort • remove designation of dosing schedule as primary and booster doses, in line with Chapter 14a • remove recommendation of 3 primary doses for severely immunosuppressed individuals • reflect change in licensing for Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/ dose dispersion for injection	13 September 2023
V3.00	UKHSA COVID-19 PGD for children and young people (aged 5 to 17 years) updated to: • remove exclusion criteria regarding individuals about to undergo new or intensified immunosuppressive treatment	29 September 2023

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)	Christina Wilson Lead Pharmacist – Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 September 2023
Doctor	Dr. Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist - Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 September 2023
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		22 September 2023

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

Name	Designation
Alex Allen	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Jane Devenish	Head of Operations and Delivery - Vaccinations, NHSE
Naveen Dosanjh	Senior Clinical Advisor, COVID-19 Vaccination Programme, NHSE
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSE
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel (see over page) in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group.

Expert panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	Pharmacist, Medicines Governance, Patient Group Directions and Medicines Mechanisms, NHS Specialist Pharmacy Service
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
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Jacqueline Lamberty	Lead Pharmacist, Medicines Governance, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Nikki Philbin	Screening and Immunisation Manager, Vaccination and Screening Programmes, NHSE Midlands.
Tushar Shah	Lead Pharmacy Adviser, NHSE London
Laura Smeaton	IDPS Programme Projects Manager and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening (IDPS) Programme, NHS England (NHSE)

2. Organisational authorisation

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

NHSE accepts responsibility for governance of 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**	**Signed**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHSE	**Dr Simon Stockley**		28 September 2023

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 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 use 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 (continued over page)	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 and 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, 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 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 and use of the correct technique for drawing up the correct dose • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and 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-

Additional requirements (continued)	assessment if an 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, 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	COVID-19 vaccination is indicated for the active immunisation of children and young people from age 5 to 17 years for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. Immunisation is indicated in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page), recommendations given in Chapter 14a of the 'Green Book' (hereafter referred to as Chapter 14a), and subsequent correspondence and publications from the UKHSA and NHSE.
Criteria for inclusion	COVID-19 vaccination should be offered to children and young people from 5 to 17 years of age in accordance with the recommendations in Chapter 14a. Individuals are eligible for different vaccines based on their age and risk group (see Table 1). **The following criteria apply to all individuals irrespective of prior COVID-19 immunisation status.** **Individuals who have not already received a dose during the current seasonal campaign,** who are**:** (i) **aged 5 to 17 years** and • in a clinical risk group, as defined in Tables 3 and 4 of Chapter 14a • included in the recommended cohort(s) for vaccination, if and when JCVI, DHSC or other appropriate authority recommend an emergency surge vaccine response is required (ii) **aged 12 to 17 years** and • are household contacts of immunosuppressed individuals of any age, as defined in Tables 3 and 4 of Chapter 14a (iii) **aged 16 or 17 years** and are • carers: those who are eligible for a carer's allowance, or who are a sole or primary carer of an elderly or disabled individual who are themselves defined as clinically vulnerable to COVID-19 infection (as defined in Chapter 14a) • employees working in care homes for older adults • frontline health and social care workers
Criteria for exclusion[2] (continued over page)	Individuals for whom valid consent has not been obtained (for further information on consent see Green Book Chapter 2). A number of UKHSA resources are available to inform consent (see Written information to be given to the individual, parent or carer section). **As of 30 June 2023, the evergreen offer of two primary doses of COVID-19 vaccine ended. Therefore, individuals who do not fall into a clinical risk or other eligible group are not eligible for vaccination.** Individuals who: • are aged 18 years and over • are aged under 5 years • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have already received a dose of COVID-19 vaccine in the last 3 months

[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, such as a PSD

Criteria for exclusion (continued)	• 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 COVID-19 mRNA vaccines • 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)
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 UK). The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of allergy (see off-label use section below and Chapter 14a). 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 leaving the premises • 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 • where applicable, advised not to drive for 15 minutes after vaccination, as fainting can occur following vaccination Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5. Special precautions, such as those outlined in Chapter 14a (flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine) 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 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 any of the Comirnaty® COVID-19 mRNA vaccines, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously. A PSD is therefore required for administering COVID-19 vaccines to these individuals. 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, particularly in adolescents. This can

[3] The Comirnaty® vaccines contain polyethylene glycol (PEG); refer to the respective SPC for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or 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 monitoring the individual's anticoagulant therapy. The individual, parent or carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barré 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 vaccination. 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 are no 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, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. As clinical deterioration can occur up to 2 weeks after infection, vaccination should be deferred until clinical recovery. 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 individual 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 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

Action to be taken if the individual is excluded (continued)	any component of the vaccine, advice should be sought from an allergy specialist. 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. Individuals who commenced but did not complete their primary course prior to the current seasonal campaign no longer require a second dose. If the individual continues to meet inclusion criteria, a dose can be given a minimum of 3 months from the date of the last administered dose, if this is possible within the campaign period. Otherwise, individuals who have never received a dose of COVID-19 vaccine and do not meet inclusion criteria, or who were previously eligible for a booster during previous campaigns but not the present one, should be reassured (or their parent or carer) that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk during a future campaign, they will then be invited for vaccination. When the seasonal vaccination campaign has ended, individuals with severe immunosuppression (as defined in Boxes 1 and 2 of Chapter 14a) can be considered for vaccination outside of campaign periods, in accordance with the Green Book. A decision to proceed would be subject to individual clinical decision and therefore a PSD should be used to administer the vaccine. If COVID-19 vaccine has been given in the preceding 3 months, advise the individual to return when they are next invited forward for vaccination, which may coincide with the next seasonal vaccine campaign. 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 individual 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 or 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. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	**Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)** This is a multidose vial which **must not be diluted**. One vial (2.25ml) contains 6 doses of 0.3ml. One dose (0.3ml) contains 30 micrograms of raxtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles). This product is supplied in vials with a grey plastic cap.
	Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) This is a multidose vial which **must not be diluted**. One vial (2.25ml) contains 6 doses of 0.3ml. One dose (0.3ml) contains 10 micrograms of raxtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles). This product is supplied in vials with a dark blue plastic cap.
	Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) This is a multidose vial which **must not be diluted.** One vial (2.25ml) contains 6 doses of 0.3ml. One dose (0.3ml) contains 15 micrograms of tozinameran and 15 micrograms of famtozinameran, embedded in lipid nanoparticles. The product is supplied in vials with a grey plastic cap.
Legal category	Prescription only medicine (POM).
Black triangle▼	All recommended COVID-19 vaccines are black triangle products. As new vaccine products, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products.
Off-label use (continued over page)	**Allergy** The SPCs for all strengths of Comirnaty® COVID-19 mRNA vaccine recommend close observation for at least 15 minutes following vaccination. Following careful review of the safety data by the MHRA and advice from the Commission on Human Medicines, the 15 minute observation requirement has since been suspended for individuals who have no history of allergy, following vaccination with all COVID-19 vaccines. However, the individual, parent or 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. Where applicable, vaccinated individuals should be advised not to drive for 15 minutes after vaccination, as fainting can occur. Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5. 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 Coronavirus Yellow Card reporting scheme is strongly encouraged.

Off-label use (continued)

Storage

Vaccines 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 vaccines are 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 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 or carer the vaccine is being offered in accordance with national guidance but outside of the product licence.

Route and method of administration

General principles

The Comirnaty® COVID-19 mRNA vaccines are for administration by intramuscular injection only, preferably into the deltoid muscle of the upper arm.

Vaccines should be prepared in accordance with manufacturer's recommendations (see the product's SPC) and NHS standard operating procedures for the service.

The name of the vaccine must be checked to ensure the intended vaccine is being used (as summarised in Table 1).

Vials should be inspected for particles and discolouration not in line with the product SPC before preparation and administration. Should either occur, discard the vial in accordance with local procedures.

To extract the anticipated number of doses from a single vial, low dead-volume syringes and/or needles should be used, with a combined dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

Care should be taken to ensure a full dose is given, as outlined in Table 1. Each dose must contain the correct volume of vaccine. If a full dose cannot be extracted from the remaining amount in the vial, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.

Where the individual has been assessed as being at increased risk of bleeding, 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. The individual or carer should be informed about this risk of haematoma from the injection.

Recheck the product name, batch number and expiry date immediately prior to administration.

Comirnaty® vaccine verification

Verify that the vial has the correct coloured plastic cap and the label matches the intended vaccine to be administered.

Vaccine	Vial cap colour
Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)	Grey
Comirnaty® Omicron XBB.1.5 (10 micrograms/dose)	Dark blue
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose	Grey

Handling prior to use

Ensure vials are completely thawed prior to use.

Gently invert the vial 10 times prior to administration. Do not shake.

Prior to administration, the thawed dispersion may contain white to off-white opaque amorphous particles.

(continued over page)

<table>
<tr><td>Route and method of administration (continued)</td><td>Do not dilute the vial contents if administering Comirnaty® Omicron XBB.1.5 (30 and 10 micrograms/dose) or Comirnaty® Original/ Omicron BA.4-5.
The vials should be marked with the appropriate expiry date and time.
Preparation of individual doses
The vaccine dose should be drawn up from the vial immediately prior to administration.
Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
Withdraw the required dose of Comirnaty® COVID-19 mRNA vaccine, as outlined in Dose and frequency of administration section below.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Vaccination should be offered to children and young people eligible for the current campaign, in accordance with the recommendations from the JCVI and in Chapter 14a, at a minimum interval of 3 months from the previous dose. As the primary course has reduced from 2 doses to a single dose, there is no requirement to complete this regime before receiving a further dose.
In line with Chapter 14a, there is no requirement to administer the same vaccine brand as previously administered.
Table 1: Age specific recommendations on vaccine type and dose regimes
<table>
<tr><th>Age</th><th>Recommended COVID-19 vaccine(s)[4]</th><th>Dose</th></tr>
<tr><td>5 to 11 years old</td><td>Comirnaty® Omicron XBB.1.5 (10 micrograms/dose</td><td>0.3ml</td></tr>
<tr><td rowspan="2">12 to 17 years old</td><td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)</td><td>0.3ml</td></tr>
<tr><td>Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose</td><td>0.3ml</td></tr>
</table>
Vaccination in incompletely vaccinated or previously unvaccinated individuals
If the primary course was interrupted or delayed before Autumn 2023, doses should neither be repeated or the course resumed, in line with JCVI recommendations to change to a single dose regime. Previously unvaccinated children or young people should be offered a single dose of COVID-19 vaccine as recommended in Table 1.
The main exception would be for those about to commence immunosuppressive treatment (see Special considerations and additional information).
Interval post COVID-19 infection
Refer to Cautions section (Past history of COVID-19) for information.</td></tr>
<tr><td>Duration of treatment</td><td>See Dose and frequency of administration above.</td></tr>
<tr><td>Quantity to be supplied and administered</td><td>As per Table 1.</td></tr>
</table>

[4] As outlined in the Green Book, vaccines that target the latest variant are preferable. However, an available, authorised and age-appropriate vaccine should be offered without delay, particularly to individuals at highest risk.

Supplies

Providers will receive COVID-19 vaccines via the national appointed supply route for the provider.

NHS standard operating procedures should be followed for appropriate supply, storage, handling, preparation, administration and waste minimisation of COVID-19 mRNA vaccines, which ensure use is in accordance with product's SPC and official national recommendations. Further information is also available in the Green Book Chapter 3.

Storage

General advice

Store at 2°C to 8°C. Do not freeze. Thawed vaccines should not be re-frozen.

Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. 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.

Table 2: Summary of vaccine handling and storage (thawed product)

Vaccine product	Transportation time	Product shelf life		
		Thawed vial (unopened)	Punctured vial	Temperature deviations
Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)	Up to 10 weeks at 2°C to 8°C (within the 18 month shelf life) Punctured vial: up to 6 hours at 2°C to 30ºC	10 weeks at 2°C to 8°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
Comirnaty® Omicron XBB.1.5 (10 micrograms/dose)	Up to 10 weeks at 2°C to 8°C (within the 12 month shelf life) Punctured vial: up to 6 hours at 2°C to 30ºC			
Comirnaty® Original/Omicron BA.4-5 (15 /15 micrograms) bivalent	Up to 10 weeks at 2˚C to 8˚C (within the 24 month shelf life) Punctured vial: 6 hours at 2°C to 30°C	10 weeks at 2°C to 8°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)

(continued over page)

Storage (continued)	**Thawed vial** Up to 10 weeks storage and transportation at 2°C to 8°C within the overall product shelf life. If the vaccine is received at 2°C to 8°C it should be stored at 2°C to 8°C. Except where a shelf-life extension applies, the 10 week shelf life should not exceed the printed manufacturer's expiry date (EXP) on the outer carton. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8°C to 30°C. Thawed vials can be handled in room light conditions. Once thawed, the vaccine should not be re-frozen. **Punctured vial** Chemical and physical in-use stability has been demonstrated for 12 hours at 2ºC to 30ºC, which includes up to 6 hours transportation time for all Comirnaty® products in scope of this PGD. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used as soon as practicably possible. Otherwise, in-use storage times and conditions are the responsibility of the user. **Special precautions for storage** Store in original packaging to protect from light. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
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 NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.
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. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions (continued over page)	The most frequent adverse reactions in children and young people 5 to 17 years of age are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia and chills. Very rare cases of myocarditis and pericarditis have been observed following COVID-19 mRNA 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

Identification and management of adverse reactions (continued)	pericarditis. Individuals, parents and 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. Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting. Individuals, parents and 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	The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals, parents and 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. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. 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 the individual, parent or carer	Ensure the individual, parent or carer has been provided with appropriate written information such as the: • Patient Information Leaflet (PIL) for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose), Comirnaty® Omicron XBB.1.5 (10 micrograms/dose), or Comirnaty® Original/Omicron BA.4-5 (15 micrograms/15 micrograms) COVID-19 mRNA vaccine as appropriate • 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 • a guide for eligible children and young people aged 12 to 17 • COVID-19 vaccination: women who are pregnant or breastfeeding • waiting after COVID-19 vaccination For resources in accessible formats and alternative languages, please visit Health Publications - Home. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and follow up treatment	The 15 minute observation following vaccination with COVID-19 vaccines has been suspended for 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 premises • 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
(continued over page)	

Advice and follow up treatment (continued)	14a, Table 5. Inform the individual, parent or carer of possible side effects and their management. Where applicable, individuals should be advised not to drive for 15 minutes after vaccination, as fainting can occur. The individual, parent or 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 or carer should be advised to seek immediate medical attention, should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual, parent or 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 by searching 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 or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine. When applicable, advise the individual, parent or 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). **Individuals vaccinated abroad** Children and young people who have been vaccinated abroad are likely to have received an mRNA vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice may be found in COVID-19 vaccination programme: information for healthcare practitioners. **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 to prevent any further delay in protection and 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, influenza, MenACWY and Td-IPV vaccines in the school age programmes and pertussis in pregnancy). Where co-administration does occur, the individual, parent or carer should be informed about the likely timing of potential adverse events relating to each vaccine. **Previous incomplete vaccination** Vaccination can be resumed provided a minimum interval of 3 months has been observed and the individual continues to be eligible for the current seasonal campaign.

Special considerations and additional information (continued)	There is no need to administer extra doses to compensate for previously missed primary or booster doses, even if the individual was previously eligible. **Immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Individuals who had received brief immunosuppression (≤2mg/kg prednisolone per day) for an acute episode of asthma and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. **Individuals with severe immunosuppression** The need for additional doses for individuals who have severe immunosuppression (as defined by Box 1 or Box 2 Chapter 14a) should be at the discretion of the individual's specialist. A minimum 3 month interval between doses is recommended. However, for individuals about to receive planned treatment, a minimum interval of 3 weeks between COVID-19 doses may be followed, to enable the vaccine to be given whilst the individual's immune system is better able to respond. Ideally, vaccination should take place 2 weeks before immunosuppressive treatment commences, or until 2 weeks after the period of immunosuppression, in addition to time needed for clearance of the therapeutic agent. If not possible, consideration could be given to vaccination during a treatment holiday or when the degree of immunosuppression is at a minimum. Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment. More information on optimal timing of doses for this group may be found in Chapter 14a. Such individuals should receive a dose under a PSD. 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 via a PSD. **Pregnancy** There is no known risk associated with being given a non-live vaccine during pregnancy (see Chapter 14a). In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. Because of wider experience with mRNA vaccines, these are the preferred vaccines to offer to those who are pregnant. **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the female, along with her clinical need for immunisation against COVID-19.
Records (continued over page)	The practitioner must ensure the following is recorded: • 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

Records (continued)	• 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	**COVID-19 mRNA vaccines** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 4 September 2023 https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) COVID-19 mRNA vaccine. Updated 5 September 2023 https://www.medicines.org.uk/emc/product/15042/smpc • Summary of Product Characteristics for Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) COVID-19 mRNA vaccine. Updated 6 September 2023 https://www.medicines.org.uk/emc/product/15043/smpc • Summary of Product Characteristics for Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose COVID-19 mRNA vaccine. Updated 4 September 2023 https://www.medicines.org.uk/emc/product/14457/smpc • Joint Committee on Vaccination and Immunisation (JCVI) statement on the COVID-19 vaccination programme for autumn 2023 – update 7 July 2023. Published 30 August 2023 https://www.gov.uk/government/publications/covid-19-autumn-2023-vaccination-programme-jcvi-update-7-july-2023/jcvi-statement-on-the-covid-19-vaccination-programme-for-autumn-2023-update-7-july-2023 • COVID-19 vaccination programme. Updated 8 August 2023. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 20 October 2022. 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 20 October 2022. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19 vaccination programme: information for healthcare practitioners. Updated 9 May 2023. 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. NHS England, Updated 7 March 2023 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

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Key references (continued)	• 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 • Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

7. Practitioner authorisation sheet

COVID-19 mRNA vaccine PGD (5 to 17 years of age) v3.00
Valid from: 6 October 2023 Expiry: 1 April 2024

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.