



Publications approval reference: PRN01271

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: v4.00
Valid from: 8 April 2024
Expiry date: 30 June 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 in England.

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 2012¹ (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


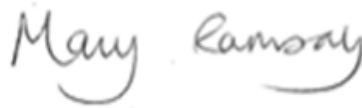

¹ This includes any relevant amendments to legislation

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	<p>UKHSA COVID-19 PGD for children and young people (aged 5 to 17 years) updated to:</p> <ul style="list-style-type: none"> 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	<p>UKHSA COVID-19 PGD for children and young people (aged 5 to 17 years) updated to:</p> <ul style="list-style-type: none"> remove exclusion criteria regarding individuals about to undergo new or intensified immunosuppressive treatment 	29 September 2023
v4.00	<p>UKHSA COVID-19 PGD for children and young people (aged 5 to 17 years) updated to:</p> <ul style="list-style-type: none"> define individuals in scope for the Spring 2024 seasonal vaccination campaign reflect changes in recommended vaccines; removal of Comirnaty® Original/ Omicron BA.4-5 reflect Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) increased manufacturer shelf life (previously 12 months) remove publications withdrawn since the last vaccination campaign reflect the new title of NHSE (HTM 07-01) guidance 	20 March 2024

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		19 March 2024
Doctor	Dr. Mary Ramsay CBE Director of Public Health Programmes and Consultant Epidemiologist - Immunisation and Vaccine Preventable Diseases Division, UKHSA		19 March 2024
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKHSA		19 March 2024

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 Implementation – adult vaccinations, NHSE
Naveen Dosanjh	Senior Clinical Advisor- Medicines and Pharmacy (Vaccinations), NHSE
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, 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 Committee.

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
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Shamez Ladhani	Paediatric Infectious Disease Consultant, UKHSA
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Lockett	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
Director of Vaccination, NHSE	Caroline Temmink		19 March 2024

[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

<p>Qualifications and professional registration</p>	<p>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):</p> <ul style="list-style-type: none"> • 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 <p>Practitioners must also fulfil all of the Additional requirements</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • 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-assessment if an experienced vaccinator (vaccinated within past 12 months) • should fulfil any additional requirements defined by local or national policy <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>

Continued training requirements	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis.</p> <p>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA, NHSE and other sources of medicines information.</p>
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4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>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.</p>
<p>Criteria for inclusion</p>	<p>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.</p> <p>Individuals are eligible for different vaccines based on their age (see Table 1).</p> <p>The following criteria apply to all individuals irrespective of prior COVID-19 immunisation status.</p> <p>Individuals who have not already received a dose during the current seasonal campaign aged 5 to 17 years, who are:</p> <ul style="list-style-type: none"> (i) immunosuppressed, as defined in the immunosuppression section of either Table 3 or 4, Chapter 14a (ii) 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
<p>Criteria for exclusion²</p>	<p>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).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • 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 • 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 process³ 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)
<p>Cautions, including any relevant action to be taken</p> <p>(continued over page)</p>	<p>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).</p> <p>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).</p>

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

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)

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 injections, laxatives)
- 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. Unless at least one dose of the same vaccine has been previously tolerated, it is advisable to seek advice from an allergy specialist (for further information, see [Chapter 14a](#)).

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 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.

(continued over page)

Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in [Chapter 14a](#)). Healthcare

<p>Action to be taken if the individual is excluded (continued)</p>	<p>and therefore a PSD should be used to administer the vaccine.</p> <p>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 COVID-19 campaign.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken.</p>
<p>Action to be taken if the individual or carer declines treatment</p>	<p>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.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p>Arrangements for referral</p>	<p>As per local policy.</p>

5. Description of treatment

<p>Name, strength and formulation of drug</p>	<p>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</p> <p>This is a multidose vial which must not be diluted.</p> <p>One vial (2.25ml) contains 6 doses of 0.3ml.</p> <p>One dose (0.3ml) contains 30 micrograms of raxtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).</p> <p>This product is supplied in vials with a grey plastic cap.</p> <p>Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</p> <p>This is a multidose vial which must not be diluted.</p> <p>One vial (2.25ml) contains 6 doses of 0.3ml.</p> <p>One dose (0.3ml) contains 10 micrograms of raxtozinameran, a COVID-19 mRNA vaccine (embedded in lipid nanoparticles).</p> <p>This product is supplied in vials with a blue plastic cap.</p>
<p>Legal category</p>	<p>Prescription only medicine (POM).</p>
<p>Black triangle ▼</p>	<p>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.</p>
<p>Off-label use</p>	<p>Allergy</p> <p>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.</p> <p>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.</p> <p>Where applicable, vaccinated individuals should be advised not to drive for 15 minutes after vaccination, as fainting can occur.</p> <p>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.</p> <p>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.</p> <p>Storage</p> <p>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.</p> <p>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 outside of product licence but in accordance with national guidance.</p>

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.

Vials should be inspected for foreign particulate matter and other variation of expected appearance not in line with the product [SPC](#) before preparation and administration. Should either occur, discard the vial in accordance with local procedures.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

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 0.3ml dose is given. 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)	Blue

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.

Do not dilute the vial contents.

The vials should be marked with the appropriate expiry date and time. From a microbiological point of view, the product should be used as soon as practicably possible once opened.

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.

<p>Dose and frequency of administration</p>	<p>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 of COVID-19 vaccine.</p> <p>In line with Chapter 14a, there is no requirement to administer the same vaccine brand as previously administered.</p> <p>Table 1: Age-specific recommendations on vaccine type and dose regimes</p> <table border="1" data-bbox="371 360 1482 613"> <thead> <tr> <th>Age</th> <th>Recommended COVID-19 vaccine(s)⁴</th> <th>Dose</th> </tr> </thead> <tbody> <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>12 to 17 years old</td> <td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)</td> <td>0.3ml</td> </tr> </tbody> </table> <p>Note: use of alternative variant vaccines is not covered by this PGD and requires a PSD.</p> <p>Vaccination in incompletely vaccinated or previously unvaccinated individuals</p> <p>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.</p> <p>The main exception would be for those about to commence immunosuppressive treatment (see Special considerations and additional information).</p>	Age	Recommended COVID-19 vaccine(s) ⁴	Dose	5 to 11 years old	Comirnaty® Omicron XBB.1.5 (10 micrograms/dose)	0.3ml	12 to 17 years old	Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)	0.3ml
Age	Recommended COVID-19 vaccine(s) ⁴	Dose								
5 to 11 years old	Comirnaty® Omicron XBB.1.5 (10 micrograms/dose)	0.3ml								
12 to 17 years old	Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)	0.3ml								
<p>Duration of treatment</p>	<p>See Dose and frequency of administration above.</p>									
<p>Quantity to be supplied and administered</p>	<p>As per Table 1.</p>									
<p>Supplies</p>	<p>Providers will receive COVID-19 vaccines via the national appointed supply route for delivery of NHS-commissioned services.</p> <p>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.</p>									
<p>Storage</p> <p>(continued over page)</p>	<p>General advice</p> <p>Store at 2°C to 8°C. Do not freeze. Thawed vaccines should not be re-frozen. Store in original packaging to protect from light if not in use.</p> <p>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.</p> <p>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.</p>									

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, in preference to a substantial delay to vaccination with a slightly better matched vaccine.

Storage (continued)	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)	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)	Punctured vial: up to 6 hours at 2°C to 30°C				
<p>Thawed vial</p> <p>Up to 10 weeks storage and transportation at 2°C to 8°C within the overall product shelf life.</p> <p>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.</p> <p>Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8°C to 30°C.</p> <p>Thawed vials can be handled in room light conditions.</p> <p>Once thawed, the vaccine cannot be re-frozen.</p> <p>Punctured vial</p> <p>Chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 30°C, 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.</p> <p>Special precautions for storage</p> <p>Store in original packaging to protect from light.</p> <p>During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p>					
Disposal	<p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <p>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): safe and sustainable management of healthcare waste.</p>				
Drug interactions	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>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</p>				
(continued over page)					

<p>Drug interactions (continued)</p>	<p>any safety concerns, although it may make the attribution of any adverse events more difficult.</p> <p>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.</p> <p>For further information about co-administration with other vaccines see Additional Information section.</p>
<p>Identification and management of adverse reactions</p>	<p>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.</p> <p>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 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.</p> <p>Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting.</p> <p>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.</p> <p>A detailed list of adverse reactions across all age groups is available in the product's SPC.</p>
<p>Reporting procedure of adverse reactions</p>	<p>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.</p> <p>Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.</p> <p>Chapter 8 and Chapter 14a 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 an allergic reaction.</p>
<p>Written information to be given to the individual, parent or carer (continued over page)</p>	<p>Ensure the individual, parent or carer has been provided with appropriate written information such as the:</p> <ul style="list-style-type: none"> • patient information leaflet (PIL) for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) or Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) COVID-19 mRNA vaccine as appropriate • COVID-19 Vaccination Record Card • what to expect after your child's COVID-19 vaccination • COVID-19: a guide for parents of children 6 months 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 <p>For resources in accessible formats and alternative languages, please visit Health Publications - Home. Where applicable, inform the individual, parent or carer that large</p>

<p>Written information to be given to the individual, parent or carer (continued)</p>	<p>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.</p>
<p>Advice and follow up treatment</p>	<p>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).</p> <p>Following COVID-19 vaccine administration, individuals without a history of allergy should be:</p> <ul style="list-style-type: none"> 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 the leaflet What to expect after your child's COVID-19 vaccination, or other age-appropriate information, as applicable) <p>Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5.</p> <p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>Where applicable, individuals should be advised not to drive for 15 minutes after vaccination, as fainting can occur.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent vaccine dose is due.</p>
<p>Special considerations and additional information</p> <p>(continued over page)</p>	<p>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.</p> <p>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.</p> <p>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).</p> <p>Individuals vaccinated abroad</p> <p>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.</p>

Special considerations and additional information
(continued)

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. There is no need to administer extra doses to compensate for previously missed 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 ($\leq 2\text{mg/kg}$ 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

Regardless of the time of year or previous vaccination history, additional doses of COVID-19 vaccine may be considered for individuals with severe immunosuppression (as defined by either Box 1 or Box 2: Criteria for additional doses of COVID-19 vaccine, [Chapter 14a](#), as applicable to the individual's age).

The need for additional doses and the optimal dose intervals should be at the discretion of the individual's specialist. In such circumstances, the dose should be given under a PSD.

More information on timing of additional doses may be found in [Chapter 14a](#).

Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment.

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). Revaccination with COVID-19 vaccine 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

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<p>Special considerations and additional information (continued)</p>	<p>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.</p>
<p>Records</p>	<p>The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> • 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 the individual is excluded or the individual, (or parent or carer) declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.</p>

6. Key references

<p>Key references</p> <p>(continued over page)</p>	<p>COVID-19 mRNA vaccines</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 21 February 2024 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 7 March 2024 https://www.medicines.org.uk/emc/product/15042/smhc• Summary of Product Characteristics for Comirnaty® Omicron XBB.1.5 (10 micrograms/dose) COVID-19 mRNA vaccine. Updated 7 March 2024 https://www.medicines.org.uk/emc/product/15043/smhc• Joint Committee on Vaccination and Immunisation (JCVI) statement on COVID-19 vaccination in spring 2024 and considerations on future COVID-19 vaccination, 4 December 2023. Published 7 February 2024• COVID-19 vaccination programme. Updated 9 February 2024 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 <p>General</p> <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste. NHS England, Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-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 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources• Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017 https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them• UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/ukSI/2012/1916/contents• UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/ukSI/2020/1125/contents/made• UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/ukSI/2020/1594/regulation/4/made• Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022
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Key references (continued)	https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors
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7. Practitioner authorisation sheet

COVID-19 mRNA vaccine PGD (5 to 17 years of age) v4.00

Valid from: 8 April 2024 Expiry: 30 June 2024

Practitioner

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

PGDs do not remove inherent professional obligations or accountability.

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

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

Name	Designation	Signature	Date

Authorising manager

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

Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.