UK Health Security Agency

NHS England

Publications approval reference: PRN01272

COVID-19 vaccine (adults) Patient Group Direction

This Patient Group Direction (PGD) is for the administration of COVID-19 vaccines to individuals 18 years and over, in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of COVID-19 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 vaccine (adults) PGD
Version no:	v5.00
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 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHSE. Section 7 is to be completed by registered practitioners providing the service and their authorising 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 8 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 that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA developed COVID-19 vaccine PGDs can be found via: COVID-19 vaccination programme.

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

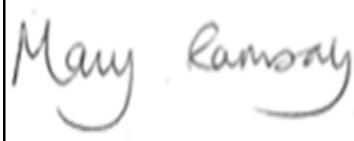
[1] This includes any relevant amendments to legislation

Change history

Version	Change details	Date
v1.00 and v2.00	See previous versions of this PGD for details of the change history.	27 March 2023 to 5 September 2023
v3.00	UKHSA COVID-19 vaccine (adults) PGD updated to: • include dose, handling, administration and storage details for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection • reflect change in manufacturer shelf life from 18 months to 24 months for Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection • reflect change in licensing for Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection • clarify that individuals about to commence or undergo new or intensified immunosuppressive treatment should receive a dose under PSD (see Criteria for exclusion)	13 September 2023
v4.00	UKHSA COVID-19 vaccine (adults) PGD updated to: • include dose, handling, administration and storage details for Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection	26 September 2023
v5.00	UKHSA COVID-19 vaccine (adults) PGD updated to: • define individuals in scope for the Spring 2024 seasonal vaccination campaign • reflect changes in recommended vaccines; removal of Comirnaty® Original/ Omicron BA.4-5, Spikevax® bivalent Original/Omicron BA.4-5 and VidPrevtyn Beta® • remove publications withdrawn since the last seasonal vaccination campaign • reflect increased transportation limits for Spikevax® XBB.1.5 (0.1mg/ml dispersion for injection); previously capped at 12 hours • 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, Southbourne Surgery
Gemma Hudspeth	Senior Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board
Jacqueline Lamberty	Medicines Governance Consultant Lead Pharmacist, UKHSA
Elizabeth Luckett	Senior Screening & Immunisation Manager, NHSE South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Nikki Philbin	Screening and Immunsation 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

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 completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session and/or locally provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or a 'best interests' decision in accordance with the Mental Capacity Act 2005) 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

Additional requirements (continued)	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 individuals 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 Immunisation Against Infectious Disease: 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 individuals aged 18 years and over in accordance with the recommendations in Chapter 14a. **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**:** • aged 75 years and over, including those due to turn 75 years of age on or before 30 June 2024 • residents in a care home for older adults • individuals aged 18 to 74 years who are immunosuppressed, as defined in the immunosuppression section of Table 3, 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
Criteria for exclusion[2]	Individuals for whom valid consent, or a 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of the Green Book). Several UKHSA resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • are under 18 years of age • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have 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 vaccine or to any component or residue[3] from the manufacturing process in the vaccine • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination)

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

[3] Refer to the product SPC for a full list of excipients.

Cautions, including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of an allergic reaction (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 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. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5. 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 have a polyethylene glycol (PEG) component (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.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. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination.

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Cautions, including any relevant action to be taken (continued)	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 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. On a precautionary basis, where GBS occurred within 6 weeks of an Astra Zeneca vaccine, mRNA COVID-19 vaccines are preferred for subsequent doses. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. 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 is given (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. There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19. During care home outbreaks, vaccination of residents with confirmed COVID-19 can proceed, provided that individuals are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this approach maximises vaccination coverage without the need for multiple visits. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Action to be taken if the patient is excluded	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient-specific basis, under a PSD. For individuals who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. Any subsequent dose should be provided by an appropriate prescriber, 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, 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 (see Chapter 14a for further details). 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 dose during previous campaigns but not the present one, should be reassured 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 of COVID-19 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 Box 1 of Chapter 14a) can be considered for vaccination outside of campaign periods, as described in 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 COVID-19 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. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. Advise the individual 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)** One dose (0.3ml) contains: 30 micrograms of raxtozinameran (embedded in lipid nanoparticles) **Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection** One dose (0.5ml) contains: 50 micrograms of andusomeran (embedded in SM-102 lipid nanoparticles).
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	**Allergy** According to the Comirnaty® SPC, it is recommended that all recipients are kept for observation and monitored for a minimum of 15 minutes. 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, vaccinated individuals 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. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. 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. **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 procedures. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual or carer that the vaccine is being offered outside of product licence but in accordance with national guidance.

Route and method of administration	**General principles** Administer the required dose of COVID-19 vaccine (as outlined in Table 1) 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 vial should be inspected for foreign particulate matter and other variation of expected appearance 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. Care should be taken to ensure a full 0.3 or 0.5ml dose is administered. If a full dose cannot be extracted, the remaining vial volume must be discarded. 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 prior to administration. Specific handling requirements of each vaccine is outlined below.
(continued over page)	**a) Comirnaty® XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine** Verify that the vial has a grey plastic cap and the product name reads as Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection. The vaccine should be used or discarded by the post-thaw expiry date. Thawed vials can be handled in room light conditions. Gently mix by inverting vials 10 times prior to use. Do not shake. **Do not dilute the vial contents.** Prior to mixing, the vaccine may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a white to off-white dispersion with no particulates available. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw 0.3 ml of Comirnaty® Omicron XBB.1.5. The vaccine dose should be drawn up from the vial immediately prior to administration. Each dose must contain 0.3 ml of vaccine. Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a 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. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Record the date and time of first puncture on the vial and discard unused vaccine within 12 hours of puncture (if stored between 2°C and 30°C). From a microbiological point of view, the product should be used as soon as practicably possible once opened.

Route and method of administration (continued)	**b) Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection** Verify the vial has a blue flip-off cap and bears the correct name. Each vial contains 5 doses of 0.5ml. Thawed vials and filled syringes may be handled in room light conditions. After removing the flip-off cap, using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. **Do not shake or dilute** – the vial should be gently swirled after thawing and before each administration. Prior to injection, inspect each dose to confirm the vaccine is white to off-white in colour in both vial and syringe. The vaccine may contain white or translucent product-related particulates. Withdraw 0.5ml of Spikevax® XBB.1.5. The dose should be used immediately. Once the vial is punctured, the vial should be discarded after 6 hours. Record the date and time the vial is to be discarded onto the vial label. From a microbiological point of view, the product should be used as soon as practicably possible once opened. An additional overfill is included in each vial to ensure 5 doses of 0.5ml can be delivered. Any remaining should be discarded in line with local procedures. Where possible, the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung.

Dose and frequency of administration	Vaccination should be offered to individuals eligible for the current campaign as part of the national COVID-19 vaccination programme 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. In line with Chapter 14a, there is no requirement to administer the same vaccine brand as previously administered. **Table 1: Summary table of dosing regimes** **Vaccine[4]** / **Dose** **Comirnaty® Omicron XBB.1.5 (30 micrograms/ dose)** / 0.3ml **Spikevax® XBB.1.5 (0.1mg/ml)** / 0.5ml Note: use of alternative variant vaccines is not covered by this PGD and requires a PSD **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 individuals 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).
Duration of treatment	See Dose and frequency of administration above.

[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

Quantity to be supplied and administered

As per Table 1.

Supplies

Providers will receive COVID-19 vaccines via the national appointed supply route for delivery of NHS-commissioned services.

NHS standard operating procedures should be followed for appropriate supply, storage, handling, preparation, administration and waste minimisation of COVID-19 vaccines and to ensure use is in accordance with the 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. Store in original packaging to protect from light if not in use.

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 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)
Spikevax® XBB.1.5 (0.1mg/ml)	Up to 36 hours at 2°C to 8°C (within the 30 day* post-thaw expiry) of which 30 hours is by road	30 days* at 2°C to 8°C	Up to 6 hours at 2°C to 25ºC	Up to 24 hours at 8°C to 25°C

*where Spikevax® XBB.1.5 (0.1mg/ml) has been stored at -50°C to -15°C for between 9 to 12 months, the unopened vial must be used within a maximum of 14 days and not exceeding a total storage time of 12 months, provided once thawed, the vial is protected from light and stored at 2°C to 8°C throughout.

Specific directions pertinent to each vaccine are outlined below.

a) Comirnaty® XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine

Thawed vial

Thawed unopened vials have a 10 week shelf-life at 2°C to 8°C, including for transportation.

If the vaccine is received at 2°C to 8°C it should be stored at 2°C to 8°C. Except where

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Storage (continued)	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 cannot be re-frozen. **Punctured vial** Shelf life of the punctured vial is 12 hours at 2°C to 30°C, which includes up to 6 hours transportation time. From a microbiological point of view, the product should be used as soon as practicably possible once opened. **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.
	b) Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection **Thawed vial** Thawed unopened vials must be stored at 2°C to 8°C and used within the post-thaw expiry date, indicated on the outer packaging. (Note: vials kept in a frozen state for between 9 and 12 months will be given a reduced 14 day thaw expiry). Within this period, up to 36 hours may be used for transportation; a maximum of 30 hours by road and 6 hours by airfreight. The post thaw expiry should not exceed the manufacturer printed expiry date (EXP) on the outer carton, except where a shelf-life extension is advised. Prior to use, the unopened vial can be stored for up to 24 hours at 8°C to 25°C Once thawed at 2°C to 8°C, vials must not be refrozen. **Punctured vial** After initial puncture, the shelf life of the punctured vial is 6 hours at 8°C to 25°C, within a 24 hour expiry if stored unopened between 8°C to 25°C and not exceeding the post-thaw expiry date. From a microbiological point of view, the product should be used as soon as practicably possible. In-use storage times and conditions are the responsibility of the user.

Disposal	Follow local clinical waste policy and NHS standard operating procedures to 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): safe and sustainable management of healthcare waste.
Drug interactions (continued over page)	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating)

Drug interactions (continued)	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	The most frequently reported adverse reactions are injection-site pain, swelling or redness, fatigue, headache, myalgia, chills, arthralgia, pyrexia, nausea, diarrhoea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Very rare cases of myocarditis and pericarditis have been observed following vaccination with both Comirnaty® and Spikevax®. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. 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. Vaccinated individuals 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 COVID-19 vaccination. In most cases, this is self-limiting. Individuals (or their carers) should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions	As new products, MHRA has a specific interest in the reporting of all adverse drug reactions for all COVID-19 vaccines. Healthcare professionals, individuals and carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme or by searching 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 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.
Written information to be given to individual or carer	Ensure the individual 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), or Spikevax® XBB.1.5 (0.1mg/ml) COVID-19 vaccine as applicable • COVID-19 vaccination record card • what to expect after your COVID-19 vaccination • COVID-19 vaccination: women who are pregnant or breastfeeding For resources in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual 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 period 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 the leaflet What to expect after your COVID-19 vaccination). • individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Inform the individual or carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The individual 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. Vaccinated individuals or their carers 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 or carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme or 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. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. When applicable, advise the individual or carer when to return for vaccination or when a subsequent vaccine dose is due.

Special considerations and additional information	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. **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 for 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 woman, along with her clinical need for immunisation against COVID-19. **Participants in clinical trials** Trial participants who are eligible for a booster dose should be offered vaccination in line with the general population, at least 3 months after any previous doses. **Individuals vaccinated abroad** Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice 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 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 influenza, shingles and pneumococcal polysaccharide vaccines in those aged over 65 years and pertussis-containing and influenza vaccines in pregnancy. Where co-administration does occur, the individual 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.

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Special considerations and additional information (continued)	**Immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) 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 Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above, Chapter 14a). 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, including 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 PSD.
Records	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. It is important that vaccinations are recorded in a timely manner on appropriate healthcare 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	• Summary of Product Characteristics, Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine, last updated 8 January 2024 • Summary of Product Characteristics, Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection, last updated 21 February 2024 • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 21 February 2024 COVID-19: the green book, chapter 14a - GOV.UK • UK Chief Medical Officers Report; suspension of the 15 minute wait for vaccination with mRNA vaccine for COVID-19, 14 December 2021 • 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 www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 20 October 2022 www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 20 October 2022 www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19 vaccination programme: information for healthcare practitioners.Updated 9 May 2023 www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste. NHS England. Updated 7 March 2023 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 www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated 4 January 2018 www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017 www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 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

7. Practitioner authorisation sheet

COVID-19 vaccine (18 years and over) PGD v5.00
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 towork 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.