UK Health Security Agency

NHS England

Publications approval reference: PRN01868

COVID-19 mRNA vaccine (5 years and over) Patient Group Direction

This Patient Group Direction (PGD) is for the administration of COVID-19 mRNA vaccine to eligible individuals from the age of 5 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 (5 years and over) PGD
Version no:	v2.0
Valid from:	1 April 2025
Expiry date:	17 June 2025

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 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012[1] (HMR2012) Schedule 16 Part 2, on behalf of NHSE. Section 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. Section 7 cannot be used to alter, amend to or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations. 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. This PGD should also be kept by the provider organisation for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children.

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 are also reminded to ensure vaccination is in

[1] This includes any relevant amendments to legislation

line with the contractual arrangements and limitations of service provision agreed with the service commissioner as well as the criteria for inclusion.

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

Change history

Version	Change details	Date
v1.0	New UKHSA combined PGD to support delivery of the Autumn 2024 COVID-19 vaccination programme to eligible individuals aged 5 years and over. This PGD reflects the change in antigenic content of the COVID-19 vaccine, from XBB (as utilised in Autumn 2023 and Spring 2024 campaigns) to JN.1. The PGD also amalgamates the 2 previously separate PGDs for adults and children aged 5 to 17 years, into a single legal framework.	6 September 2024
v2.0	UKHSA COVID-19 PGD updated to include: • eligibility criteria for Spring 2025 • updated references and hyperlinks	18 February 2025

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 Programmes, UKHSA		14 February 2025
Doctor	Dr Alex Allen Consultant Epidemiologist – Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 February 2025
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA		14 February 2025

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

Name	Designation
Naveen Dosanjh	Senior Clinical Advisor- Medicines and Pharmacy (Vaccinations), NHSE
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Jo Jenkins	Associate Director Medicines Governance, Medicines Use and Safety, NHS Specialist Pharmacy Service
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA

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

Expert panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
Alison Campbell	Screening and Immunisation Coordinator, Clinical, NHSE Midlands
Rosie Furner	Advanced Specialist Pharmacist – Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Elizabeth Luckett	Senior Screening and Immunisation Manager, Screening and Immunisation Team – Kent and Medway, NHSE South East
Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Briony Mason	Vaccination Manager, NHSE West Midlands
Tushar Shah	Lead Pharmacy Adviser, NHSE London

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, contractual arrangements with the Commissioner and relevant standard operating procedures (SOPs) 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**		14 February 2025

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.

3. Characteristics of staff

Qualifications and professional registration	**All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below.** **Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD:** • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians 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
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply 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 have undertaken training appropriate to this PGD as required by local policy and SOPs and in line with 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 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 **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 immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). 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 eligible individuals from the age of 5 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), JCVI and subsequent correspondence and publications from the UKHSA and NHSE.
Criteria for inclusion	**Individuals who have not already received a dose during the current seasonal campaign** who are: (i) aged 5 years to 74 years who are immunosuppressed, as defined in the immunosuppression section of either table 3 or 4 of Chapter 14a (ii) residents in a care home for older adults (iii) aged 75 years and over, including those due to turn 75 of years on or before 17 June 2025
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 resources are available to inform consent (see written information to be given to the individual, parent or carer section). Individuals who: • 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 process[3] in the COVID-19 mRNA vaccines • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe illness (the presence of a minor infection is not a contraindication for vaccination)
Cautions, including any relevant action to be taken (continued over page)	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of allergy (see off-label use section below and Chapter 14a).

[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)	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. 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. Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk-benefit is in favour of vaccination. Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2 to 5 days after the vaccine (British Society for Haematology-COVID-19). **Past history of COVID-19 infection** There are no safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. 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. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Action to be taken if the individual is excluded	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient-specific basis, under a PSD. 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. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. 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, the current advice is that an individual's 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 dose during previous campaigns but not the present one, should be reassured (or their parent or carer) that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk 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 Boxes 1 and 2 of Chapter 14a) can be considered for vaccination outside of campaign periods, in accordance with the Green Book. A decision to proceed would be subject to individual clinical decision and therefore a PSD should be used to administer the vaccine. If COVID-19 vaccine has been given in the preceding 3 months, advise the individual to return when they are next invited forward for vaccination, which may coincide with the next seasonal COVID-19 campaign. Document the reason for exclusion and any action taken.
Action to be taken if the individual, parent 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. In the case of individuals under 16 years, consent of someone with parental responsibility should be sought, unless the individual is assessed as being Gillick competent. For further information on consent, see Chapter 2 of the Green Book. Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.

Arrangements for referral	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	• **Comirnaty® JN.1 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified).** Each vial contains a single dose of 0.3ml. One dose (0.3ml) contains 10 micrograms of bretovameran, embedded in lipid nanoparticles. • **Comirnaty® JN.1 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified).** One vial (2.25ml) contains 6 doses of 0.3ml. One dose (0.3ml) contains 30 micrograms of bretovameran, embedded in lipid nanoparticles. • **Spikevax® JN.1 (0.1mg/ml) dispersion for injection.** One vial (2.5ml) contains 5 doses of 0.5ml. One dose (0.5ml) contains 50 micrograms of mRNA-1273.167
Legal category	Prescription only medicine (POM).
Black triangle▼	Yes - 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** 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. Individuals (or their parent or carer) should be counselled in line with the relevant points from the advice and follow-up treatment section. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the 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. Where a vaccine is recommended off-label, as part of the consent process consider informing the individual, parent or carer the vaccine is being offered in accordance with national guidance but outside of product licence.

Route and method of administration

General principles

Ensure vials are completely thawed prior to use.

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

Unopened vials should be used or discarded by the post-thaw expiry date indicated on the outer packaging.

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.

Do not shake or dilute the vial contents. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. Thawed vials may be handled in room light conditions.

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

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.

Care should be taken to ensure a full 0.3ml or 0.5ml 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 possible, the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician 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 be vaccinated via the intramuscular route. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. 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, parent or carer should be informed about the risk of haematoma from the injection.

Immediately prior to administration, recheck the product name, batch number, dose volume and post-thaw expiry date, including the expiry date and time of the punctured vial.

Specific handling requirements for each of the vaccines are outlined below.

a) Comirnaty® JN.1 (10 micrograms/dose and 30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine

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® JN.1 (10 micrograms/dose)	Blue
Comirnaty® JN.1 (30 micrograms/dose)	Grey

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

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

To extract the anticipated number of doses from a multidose vial, low dead-volume

(continued over page)

<table>
<tr><td rowspan="2">Route and method of administration
(continued)</td><td>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.</td></tr>
<tr><td>b) Spikevax JN.1 (0.1mg/ml) dispersion for injection
Verify the vial bears the correct name. 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.</td></tr>
<tr><td>Dose and frequency of administration</td><td>Vaccination should be offered to individuals 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.
In line with Chapter 14a, there is no requirement to administer the same vaccine brand as previously administered.
Table 1: Age-specific recommendations on vaccine type and dose regimes
<table>
<tr><th>Age</th><th>Recommended COVID-19 vaccine(s)[4]</th><th>Dose</th></tr>
<tr><td>5 to 11 years old</td><td>Comirnaty® JN.1
(10 micrograms/dose)</td><td>0.3ml</td></tr>
<tr><td>12 to 17 years old</td><td>Comirnaty® JN.1
(30 micrograms/dose)</td><td>0.3ml</td></tr>
<tr><td rowspan="2">18 years and over</td><td>Comirnaty® JN.1
(30 micrograms/dose)</td><td>0.3ml</td></tr>
<tr><td>Spikevax® JN.1
(0.1mg/ml)</td><td>0.5ml</td></tr>
</table>
Note: use of alternative variant vaccines such as XBB are not covered by this PGD.</td></tr>
<tr><td>Duration of treatment</td><td>See dose and frequency of administration above.</td></tr>
<tr><td>Quantity to be supplied and administered</td><td>A single dose, as outlined for the individual’s age in Table 1.</td></tr>
<tr><td>Supplies</td><td>Providers will receive COVID-19 vaccines via the national appointed supply route for delivery of NHS-commissioned services.
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 the product’s SPC and official national recommendations. Further information is also available in the Green Book Chapter 3.</td></tr>
</table>

[4] As outlined in the Green Book, vaccines that target the latest variant are preferable. However, an available, authorised and age-appropriate vaccine should be offered without delay, in preference to a substantial delay to vaccination with a slightly better matched vaccine.

Storage

(continued over page)

General advice

Store at 2°C to 8°C. Do not freeze. Thawed vaccines must 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 standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The product's SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis 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® JN.1 (10 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 30˚C	10 weeks at 2°C to 8°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
Comirnaty® JN.1 (30 micrograms/dose)				
Spikevax® JN.1 0.1mg/ml dispersion for injection	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® JN.1 (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.

Storage (continued)	**a) Comirnaty® JN.1 (10 micrograms/dose and 30 micrograms/ dose) dispersion for injection COVID-19 mRNA vaccine** **Thawed vial** Up to 10 weeks storage and transportation at 2°C to 8°C within the overall product shelf life. Except where a shelf-life extension applies, the 10 week post thaw 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 up to 30°C. Thawed vials can be handled in room light conditions. **Punctured vial** Chemical and physical in-use stability has been demonstrated for 12 hours at 2ºC to 30ºC, which includes up to 6 hours transportation time for all Comirnaty® products in scope of this PGD. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used as soon as practicably possible. Otherwise, in-use storage times and conditions are the responsibility of the user. **Special precautions for storage** During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
	b) Spikevax® JN.1 (0.1mg/ml) dispersion for injection **Thawed vial** Thawed unopened vials must be stored at 2°C to 8°C and used within the 30 day 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, provided a total storage time of 12 months has not been exceeded. 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 30 day 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 at 8°C to 25°C up to 24 hours after removal from refrigerated conditions. **Punctured vial** After initial puncture, the shelf life of the punctured vial is 6 hours at 2°C to 25°C, within a 24 hour expiry if stored unopened between 8°C to 25°C and not exceeding the 30 day 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. **Special precautions for storage** Thawed vials may be handled in room light conditions.
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	The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exist, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. For further information about co-administration with other vaccines, see additional information section.
Identification and management of adverse reactions	The most frequent adverse reactions are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia and chills. Nausea and lymphadenopathy are additional very commonly reported side-effects following immunisation with Spikevax®. Diarrhoea is a very common side effect specific to Comirnaty.® Very rare cases of myocarditis and pericarditis have been observed following COVID-19 mRNA vaccination. The reported rate is highest in individuals under 25 years and in males, usually within a few days following vaccination, after a second dose. Most cases are mild and self-limiting. The MHRA has advised the benefits from vaccination outweigh any risk in most individuals. 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. Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting. Individuals, parents and carers should be provided with the advice within the leaflet what to expect after your child's COVID-19 vaccination or what to expect after your COVID-19 vaccination as applicable, which covers the reporting of adverse reactions and their management, such as with analgesics. A detailed list of adverse reactions across all age groups is available in the product's SPC.
Reporting procedure of adverse reactions	The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals, parents and carers should report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. Chapter 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 the individual, parent or carer	Ensure the individual, parent or carer has been provided with appropriate written information such as the: • patient information leaflet (PIL) for the-administered COVID-19 mRNA vaccine as appropriate: Comirnaty® JN.1 (30 micrograms/dose) Comirnaty® JN.1 (10 micrograms/dose) Spikevax® JN.1 (0.1mg/ml) • what to expect after your child's COVID-19 vaccination • what to expect after your COVID-19 vaccination For resources in accessible formats and alternative languages, please visit Health Publications - Home. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and follow up treatment	Inform the individual, parent or carer of possible side effects and their management. The 15 minute observation following vaccination with COVID-19 vaccines has been suspended for individuals without a history of allergy (see off-label use section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the premises • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see the leaflet what to expect after your child's COVID-19 vaccination, or what to expect after your COVID-19 vaccination as applicable) • where applicable, advised not to drive for 15 minutes after vaccination, as fainting can occur following vaccination 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. No specific management is required for individuals with a family history of allergies. The individual, parent or carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Seek immediate medical attention, should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual, parent or carer they can report side effects directly via the national reporting system run by the MHRA known as the Yellow Card reporting scheme, or by searching for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine. When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent dose is due.
Special considerations and additional information (continued over page)	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.

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). When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records. Co-administration of the COVID-19 vaccine with the respiratory syncytial virus (RSV) vaccine is not routinely recommended in older adults. Refer to the RSV PGD and Chapter 27a of the Green Book for further details. 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. **Immunosuppressed** The immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Individuals who had received brief immunosuppression (≥ 40mg prednisolone per day or equivalent for children) 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 when indicated (see criteria for inclusion and Chapter 14a). **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that eligible 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

(continued over page)

Special considerations and additional information (continued)	are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19.
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 the individual, (or parent or carer) 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 health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

6. Key references

Key references (continued over page)	**COVID-19 mRNA vaccines** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Summary of Product Characteristics for Comirnaty® JN.1 (10 micrograms/dose) COVID-19 mRNA vaccine, updated 21 January 2025 https://www.medicines.org.uk/emc/product/15836/smpc • Summary of Product Characteristics for Comirnaty® JN.1 (30 micrograms/dose) COVID-19 mRNA vaccine, updated 21 January 2025 https://www.medicines.org.uk/emc/product/15834/smpc • Summary of Product Characteristics for Spikevax®JN.1 COVID-19 mRNA vaccine, updated 3 September 2024 https://www.medicines.org.uk/emc/product/15914/smpc • JCVI statement on COVID-19 vaccination in 2025 and spring 2026, updated 14 November 2024 • COVID-19 vaccination programme https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators, updated 3 October 2024 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 3 October 2024 https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19 vaccination programme: information for healthcare practitioner, last updated 3 October 2024 https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners **General** • 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-htm-07-01/ • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published 27 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 • 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 • UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 https://www.legislation.gov.uk/uksi/2024/729/introduction/made

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

7. Practitioner authorisation sheet

COVID-19 mRNA vaccine PGD (5 years and over) v2.0
Valid from: 1 April 2025 Expiry: 17 June 2025

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.