UK Health Security Agency

NHS

Publications approval reference: C1696

Patient Group Direction for Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine

This Patient Group Direction (PGD) is for the administration of Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine to individuals 12 years of age and over as a booster dose in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine by registered healthcare practitioners identified in Section 3.
The national COVID-19 vaccination programme may also be provided under national protocol or on a patient specific basis (that is by or on the direction of an appropriate independent prescriber). Supply and administration in these instances are not covered by this PGD.

Reference no:	Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine PGD
Version no:	v1.00
Valid from:	14 September 2022
Expiry date:	15 September 2023

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

NHSE and those providing services in accordance with this PGD must not alter, amend or add to the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHSE. Section 7 is to be completed by registered practitioners providing the service and their authorising/line manager.

Operation of this PGD is the responsibility of NHSE and service providers. The final authorised copy of this PGD should be kept by NHSE for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a counter signature, unless there are contractual arrangements for self-declaration.

Providers must check 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

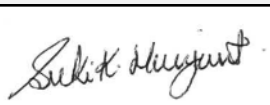
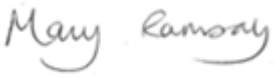
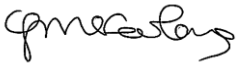
[1] This includes any relevant amendments to legislation

Change history

Version	Change details	Date
V01.00	New UKHSA Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine PGD has been written to support the Autumn booster programme 2022 for individuals aged 12 years old and over	14 September 2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 September 2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 September 2022
Registered Nurse (Chair of Expert Panel)	Lesley McFarlane Lead Immunisation Nurse Specialist Immunisation and Vaccine Preventable Diseases Division, UKHSA		14 September 2022

In addition to the signatories above the working group included:

Name	Designation
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHSE
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHSE
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSE
David Green	Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division, UKSHA
Gul Root	Principal Pharmaceutical Officer, Department of Health and Social Care and National lead pharmacy public health, Office for Health Improvement and Disparities
Naveen Dosanjh	Senior Clinical Advisor, Clinical Workstream, COVID-19 Vaccination Programme, NHSE

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSE
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, Bristol North Somerset and South Gloucestershire Integrated Care Board (ICB)
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Elizabeth Luckett	Senior Screening and Immunisation Manager NHS England South West
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSE South West
Gill Marsh	Principal Screening and Immunisation Manager, NHSE North West
Tushar Shah	Lead Pharmacy Advisor, NHSE London

2. Organisational authorisation

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

NHSE accepts governance responsibility for this PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, relevant NHS standard operating procedures (SOPs) and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

NHSE authorises this PGD for use by the services or providers delivering the national COVID-19 vaccination programme.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHSE	Dr Jonathan Leach OBE		14 September 2022

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation records, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics (SPC) and/or in accordance with official national recommendations.

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council. Practitioners must also fulfil all of the Additional requirements.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the SPC, and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant NHS standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and SOPs and in line with the Training recommendations for COVID-19 vaccinators. • must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 as required by national and local policy. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Mental Capacity Act 2005) and to discuss issues related to vaccination. For further information on consent see Chapter 2 of 'The Green Book'. • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions

Continued over page **Additional requirements** (continued)	• must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and COVID-19 vaccination programme: Information for healthcare practitioners • must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months) or have used the tool for self-assessment if experienced vaccinator (vaccinated within past 12 months) • should fulfil any additional requirements defined by local or national policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis. Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSE and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book' (hereafter referred to as Chapter 14a), and subsequent correspondence/publications from the UKHSA and/or NHSE.
Criteria for inclusion	A booster dose of Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine should be offered to individuals aged 12 years and over in accordance with the recommendations in Chapter 14a.
Criteria for exclusion[2]	Individuals for whom valid consent, or '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'). The Patient Information Leaflet (PIL) for Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine should be available to inform consent. Individuals who: • are less than 12 years of age • have not had the full primary COVID-19 vaccine course • 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 in the Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have had a full dose of COVID-19 vaccine in the preceding 3 months (see 'Action to be taken if the patient is excluded' section below)
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. The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has been removed for individuals who have no history of a severe 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 centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.

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[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

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 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 injection, laxative). • history of idiopathic anaphylaxis Individuals with undiagnosed polyethylene glycol (PEG) allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Such individuals should not be vaccinated with Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine COVID-19 vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously (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 especially in adolescents 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. Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. The individual/parent/carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of

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Cautions, including any relevant action to be taken (continued)	GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses, Pfizer or Moderna COVID-19 vaccines are preferred. 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 2-5 days after the vaccine (British Society for Haematology-COVID-19). **Past history of COVID-19 infection** There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. For children in a risk group and adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis as clinical deterioration can occur up to 2 weeks after infection. For children and young people under 18 years who are not in a risk group, vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). These recommended intervals after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSE operational guidance. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits. Current advice in Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) cases suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of

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Cautions, including any relevant action to be taken (continued)	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 (refer to the full list of excipients in the SPC), advice should be sought from an allergy specialist Any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. Individuals who have not completed their primary course should complete the recommended schedule before receiving the booster. Where the individual has had a dose of COVID-19 vaccine in the preceding 3 months, advise the individual should return at or after a 3 month period has passed since their last vaccine dose. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. 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/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) One dose (0.3 ml) contains: 15 micrograms of tozinameran (Original) a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles) and 15 micrograms of riltozinameran (Omicron BA.1), a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
Legal category	Prescription only medicine (POM).
Black triangle▼	Yes. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	**Allergy** According to the SPC, it is recommended that all recipients of the Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose vaccine are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers (CMO) recommended suspension of this requirement in December 2021. The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has since been removed for individuals who have no history of a severe allergic reaction. This follows careful review of the safety data by the MHRA and advice from the Commission on Human Medicines. 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 (see Chapter 14a). 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. 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 MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged. **Storage** Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NHS operational guidance or standard operating procedures. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Route and method of administration	Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine is for administration by intramuscular injection only, preferably into deltoid muscle of the upper arm. 2.25 ml ready to use dispersion is contained in a 2 ml clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a grey flip-off plastic cap with aluminium seal. Each vial contains 6 doses. Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection. The name of the vaccine must be checked to ensure the correct vaccine is being used. Vaccine should be prepared in accordance with manufacturer's recommendations (see the product's SPC) and NHS standard operating procedures for the service. If the multidose vial is stored frozen it must be thawed prior to use. 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours. Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C. Ensure vials are completely thawed prior to use. The unopened vial has 10 weeks shelf life when stored and transported at 2 °C to 8 °C. Upon moving the product to 2 °C to 8 °C storage, update expiry date on the outer carton. The original expiry date should be crossed out. The 10 weeks shelf life should not exceed the printed manufacturer's expiry date (EXP). The vaccine should be used or discarded by the updated expiry date. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C. Thawed vials can be handled in room light conditions. Allow the dispersion to come to room temperature prior to use. Gently mix by inverting vials 10 times prior to use. Do not shake. Prior to mixing, the thawed dispersion 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 visible. Do not use the vaccine if particulates or discolouration are present. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw 0.3 ml of Comirnaty® Original/Omicron BA.1. 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 in order 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/time of first puncture on the vial.

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Route and method of administration (continued)	Discard any unused vaccine 12 hours after first puncture. Re-check product name, batch number and expiry date prior to administration. Where the individual has been identified by the assessing registered professional 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.
Dose and frequency of administration	**Booster vaccination** A booster dose of Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA is 0.3ml containing 15 micrograms Original and 15 micrograms Omicron BA.1 COVID-19 mRNA. Booster doses should be given at a minimum interval of 3 months from the previous dose. Boosters should be offered to individuals eligible as part of the national COVID-19 vaccination programme in accordance with the recommendations from the JCVI and in Chapter 14a. Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters. **Interval post COVID-19 infection** For children in a risk group and adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen, to avoid confusing the differential diagnosis. For children and young people under 18 years who are not in a risk group vaccination after COVID-19 infection should ideally be deferred until 12 weeks from onset (or sample date). These recommended intervals after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSE operational guidance. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.
Duration of treatment	See Dose and frequency of administration above.
Quantity to be supplied and administered	Administer 0.3ml (15micrograms plus 15micrograms) per booster dose.
Supplies	COVID-19 vaccines for those authorised by the NHS to deliver the programme will be made available for ordering on the ImmForm website portal.immform.phe.gov.uk/, telephone 0207 183 8580 or through the Foundry ordering platform in England. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA Vaccine, which ensure use is in accordance with product's SPC and official national recommendations.

Storage	Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA Vaccine is supplied from the manufacturer as a multiple-dose vial of frozen, preservative-free d dispersion for injection, which requires storage at -90°C to -60°C. **Frozen Vial** Shelf life is 12 months at -90°C to -60°C The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt. When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes. **Thawed vial** Thawed unopened vials have a 10 weeks shelf-life at 2°C to 8°C. Upon moving the product to 2 °C to 8 °C storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be crossed out. If the vaccine is received at 2 °C to 8 °C it should be stored at 2 °C to 8 °C. The expiry date on the outer carton should have been updated to reflect the refrigerated expiry date and the original expiry date should have been crossed out. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C. Thawed vials can be handled in room light conditions. Once a vial is removed from the tray, it should be thawed for use. Once thawed the vaccine cannot be re-frozen. **Opened vial** Shelf life of the opened vial is 12 hours at 2 ºC to 30 ºC, which includes up to 6 hours transportation time. From a microbiological point of view the product should be used immediately once opened. **Special precautions for storage** Store in original packaging in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. These 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.
Disposal Continued over page	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and guidance in the technical

Disposal (continued)	memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines 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 (for further information see special consideration and additional information section below) A seven-day interval should ideally be observed between COVID-19 vaccination and shingles vaccination. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions	The most frequent adverse reactions in individuals 12 years of age and older are injection site pain, swelling or redness, fatigue, headache, myalgia, chills, arthralgia, pyrexia,nausea, diahorrea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Uncommon side effects include enlarged lymph nodes, feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating and night sweat. Very rare cases of myocarditis and pericarditis have been observed following vaccination with Comirnaty®. 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. Vaccinees should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. Individuals 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 Continued over page	Healthcare professionals and individuals/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. As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic

Reporting procedure of adverse reactions (continued)	reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.
Written information to be given to patient or carer	Ensure the individual has been provided appropriate written information such as the: • Patient Information Leaflet (PIL) for Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination: a guide to booster vaccination • Waiting after COVID-19 vaccination
Patient advice and follow up treatment	The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has been removed for individuals who have no history of a severe allergic reaction (see off-label section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see leaflets What to expect after your COVID-19 vaccination and Waiting after COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Inform the individual/parent/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/parent/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/parent/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.

Special considerations and additional information	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 COVID-19 vaccination. Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete the primary course before being vaccinated with a booster. **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** Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccination should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least 3 months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). **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 on Vaccination of those who received COVID-19 vaccine overseas is available from the UKHSA. **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 two or more vaccines. It is generally better for vaccination to proceed and avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings

Continued over page

Special considerations and additional information (continued)	(including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools' programmes). 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. The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. Individuals in the eligible group who have received a full course of primary vaccination (two or three doses) but have not received a booster before September 2022, may be given the autumn booster in the campaign provided it is given at a minimum interval of 3 months from the previous dose. JCVI has advised that the timeliness of vaccination is more important than the type of booster vaccine used. **Immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated.
Records	Record: • that valid informed consent was given or a decision to vaccinate 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 excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

6. Key references

Key references	**Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine**

- Immunisation Against Infectious Disease: The Green Book, Chapter 14a Updated 5 September 2022
  COVID-19: the green book, chapter 14a - GOV.UK
- UK Chief Medical Officers Report; suspension of the 15minutes wait for vaccination with mRNA vaccine for COVID-19 14 December 2021
- Summary or Product Characteristics Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/doseCOVID-19 mRNA vaccine September 2022
  Comirnaty Original/Omicron BA.1 15/15 micrograms per dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) - Summary of Product Characteristics (SmPC)
- Patient Information Leaflet Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/doseCOVID-19 mRNA vaccine September 2022
  Comirnaty Original/Omicron BA.1 15/15 micrograms per dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) - Patient Information Leaflet (PIL)
- COVID-19 vaccination programme. Updated 7 September 2022.
  www.gov.uk/government/collections/covid-19-vaccination-programme
- Training recommendations for COVID-19 vaccinators. Updated 4 October 2021.
  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 16 March 2021
  www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool
- COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022.
  www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners

General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013
  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 March 2017.
  www.nice.org.uk/guidance/mpg2/resources
- Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017.
  www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them
- UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 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

7. Practitioner authorisation sheet

Comirnaty® Original/Omicron BA.1 (15/15 micrograms)/dose COVID-19 mRNA vaccine PGD v1.00 Valid from: 14 September 2022 Expiry: 15 September 2023

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

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

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

Authorising manager

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

Note to authorising manager

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

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