



Publications approval reference: C1618

Patient Group Direction for Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine

This Patient Group Direction (PGD) is for the administration of Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine to individuals from 12 years of age in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of Comirnaty® 30micrograms/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® 30micrograms/dose COVID-19 mRNA vaccine PGD
Version no: v07.00
Valid from: 31 March 2022
Expiry date: 1 April 2023

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

NHSEI 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 NHSEI. [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 NHSEI and service providers. The final authorised copy of this PGD should be kept by NHSEI 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@phe.gov.uk

¹ This includes any relevant amendments to legislation (such as [2013 No.235](#), [2015 No.178](#), [2015 No.323](#) and [2020 No.1125](#)).

Change history




Version	Change details	Date
V01.00	New PHE PGD template for Comirnaty® COVID-19 mRNA vaccine	06/08/2021
V02.00	<p>PHE PGD template for Comirnaty® COVID-19 mRNA Vaccine V01.00 updated to:</p> <ul style="list-style-type: none"> • remove specific reference to clinically extremely vulnerable (CEV) individuals as they are covered by the inclusion of those in at risk groups • include individuals aged 12 years to under 16 years of age who are in an at-risk group (see the table 'Clinical risk groups for children aged 12-15 years' in Chapter 14a) • include other individuals from age 12 years to under 18 years of age, who do not meet any of the other criteria for inclusion, as eligible for their first dose of the COVID-19 vaccine only • include individuals referred for a third primary dose of COVID-19 vaccine in accordance with patient specific recommendations from their specialist, GP or prescriber • include individuals eligible for a booster dose as part of the national COVID-19 vaccination programme • exclude individuals who have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • move cautions relating to pregnancy and those involved in clinical trials to the additional information section • update to cautions • update the additional information on immunosuppressed individuals, co-administration and incomplete vaccination • remove key references to Joint Committee on Vaccination and Immunisation (JCVI) statements which are now incorporated into the guidance in Chapter 14a • minor wording changes and additions to text for consistency; updated references 	15/09/2021
V03.00	<p>PHE PGD template for Comirnaty® COVID-19 mRNA Vaccine V02.00 updated to:</p> <ul style="list-style-type: none"> • include second dose for individuals 16 and 17 years of age • reword criteria for inclusion • reword criteria for exclusion pertaining to allergic reactions • update cautions in line with revisions to Chapter 14a • re-write dose and frequency of administration section, to identify preferred 12week interval for those under 18 years of age and not in a risk group, to include a paragraph on minimum intervals post COVID-19 infection and to include minimum intervals for booster vaccination • include the international non-proprietary name (INN) tozinameran • update off-label section in line with revised Summary of product characteristics (SPC) • update shelf life from 6 to 9 months • update Special considerations/additional information section in line with revisions to Chapter 14a • include Appendix A • minor wording changes and additions to text for consistency and to rebrand from PHE to UKHSA; updated references 	18/11/2021
V04.00	<p>PHE PGD template for Comirnaty® COVID-19 mRNA Vaccine V03.00 updated to:</p> <ul style="list-style-type: none"> • include a 2-dose primary course for individuals aged 12 years and over • state that the recommended 12 week interval, for those under 18 years, may be reduced to 8 weeks in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). The 	02/12/2021

V04.00 continued	<p>timing of any change will be advised by JCVI or UKHSA and published in operational guidance agreed by DHSC and NHSEI.</p> <ul style="list-style-type: none"> • recommend that immunosuppressed individuals who have not yet received a third dose may be given their third dose now (8 weeks after their second dose) to avoid further delay and that a booster dose can be given to immunosuppressed individuals from 16 years of age • provide a minimum interval of 3 months between completion of primary vaccination and a booster dose • remove line stating that pregnant women should be vaccinated at the same time as non-pregnant women • update off-label section • update appendix A 	
V05.00	<p>UKHSA PGD template for Comirnaty® COVID-19 mRNA Vaccine V04.00 updated to:</p> <ul style="list-style-type: none"> • update the cautions, including any relevant action to be taken in line with updated Chapter 14a of the Green Book 14 December 2021 and UK Chief Medical Officers (CMO) report 14 December 2021 • update the off-label use section with regard to temporary removal of 15 minutes observation and monitoring requirement in line with updated Chapter 14a of the Green Book 14 December 2021 and CMO report 14 December 2021 • update off-label use section relating to booster in line with updated Chapter 14a of the Green Book 14 December 2021 • update the special considerations and additional information section with regard to use of heterologous schedules for primary immunisation in line with updated Chapter 14a of the Green Book 14 December 2021 and add subtitles • update patient advice and follow up treatment section in line with updated Chapter 14a of the Green Book 14 December 2021 and CMO report 14 December 2021 • update the key references • Updated Appendix A 	15/12/2021
V6.00	<p>UKHSA PGD template for Comirnaty® 30micrograms/dose COVID-19 mRNA Vaccine V05.00 updated to:</p> <ul style="list-style-type: none"> • amended name of vaccine to include the strength to state Comirnaty® 30micrograms/dose COVID-19 mRNA Vaccine as per the SPC dated 2 December 2021 • insert the age group to inform which age group the PGD is relevant to for clarity • update COVID-19 vaccination programme link on page 1 • provide clarity in cautions, off-label and patient advice sections for individuals without history of allergy • update cautions section to include immune thrombocytopenia (ITP) in line with the updated Chapter 14a of the Green Book 24 December 2021 • update off-label and dose and frequency sections with reference to boosting in line with the updated Chapter 14a of the Green Book 24 December 2021 • amended dose and frequency section to remove duplication • provide clarity and hyperlink for individuals without a history of allergy in patient advice section and added statement regarding individuals with history of allergy in patient advice section • update the special considerations section regarding the completion of the course at recommended intervals in pregnancy in line with the updated Chapter 14a of the Green Book 24 December 2021 • update references section • update Appendix A regarding updated booster dosing in line with the updated Chapter 14a of the Green Book 24 December 2021 	05/01/2022

V07.00	<p>UKHSA PGD template for Comirnaty® 30micrograms/dose COVID-19 mRNA Vaccine V06.00 updated to:</p> <ul style="list-style-type: none"> • move exclusions pertaining to allergy to cautions section, as special precautions, to allow for administration on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously and similarly update the actions if excluded section • reflect the revised recommendations for those with a past history of COVID-19 infection • add a paragraph to off-label section pertaining to expiry extended vaccines • update dose and frequency of administration section • update pregnancy paragraph to reflect inclusion as a risk group • clarify the vaccine that can be used to complete the primary course in those aged 12 years • update to most sections of the PGD to address the above points and for minor typographical amendment 	23/03/2022
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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)	Beth Graham Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		24/03/2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		24/03/2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division UKSHA		24/03/2022

In addition to the signatories above the working group included:

Name	Designation
Suki Hunjunt	Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHSEI
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHSEI
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSEI
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, NHSEI

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group and 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
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michael Gregory	Medical Director for Commissioning, NHSEI (North West)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSEI (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisation

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

NHSEI 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.

NHSEI 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, NHSEI	Dr Jonathan Leach OBE		28/03/2022

[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

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them):</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council. <p>Practitioners must also fulfil all of the Additional requirements.</p>
<p>Additional requirements</p>	<p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/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

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<p>Additional requirements (continued)</p>	<ul style="list-style-type: none"> • 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 <p>The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.</p>
<p>Continued training requirements</p>	<p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis.</p> <p>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSEI and other sources of medicines information.</p>

4. Clinical condition or situation to which this PGD applies

<p>Clinical condition or situation to which this PGD applies</p>	<p>Comirnaty® 30micrograms/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 NHSEI.</p>
<p>Criteria for inclusion</p>	<p>Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine should be offered to individuals aged 12 years and over in accordance with the recommendations in Chapter 14a.</p> <p>Individuals are eligible for different dose schedules based on their age and recognised risk group (see the Dose and frequency of administration section).</p>
<p>Criteria for exclusion²</p>	<p>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® 30micrograms/dose COVID-19 mRNA vaccine should be available to inform consent.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 12 years of age • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine or to any component or residue from the manufacturing process³ in the Comirnaty® 30micrograms/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 received a full dose of COVID-19 vaccine in the preceding 21 days
<p>Cautions, including any relevant action to be taken</p> <p>Continued over page</p>	<p>Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council.</p> <p>There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section below).</p> <p>Following COVID-19 vaccine administration, individuals without a history of allergy should be:</p> <ul style="list-style-type: none"> • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the 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. <p>Individuals with a personal history of allergy should be managed in line with Chapter 14a, Table 5.</p>

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

³ Contains polyethylene glycol (PEG), refer to the [SPC](#) for a full list of excipients.

Cautions, including any relevant action to be taken
(continued)

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 contain PEG (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 the Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously.

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 (equal to 23 gauge or finer calibre such as 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 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

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<p>Cautions, including any relevant action to be taken (continued)</p>	<p>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.</p> <p>Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in patients 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).</p> <p>Past history of COVID-19 infection</p> <p>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.</p> <p>Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness.</p> <p>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.</p> <p>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).</p> <p>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 NHSEI operational guidance.</p> <p>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.</p> <p>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.</p> <p>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.</p>
<p>Action to be taken if the patient is excluded</p> <p>Continued over page</p>	<p>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.</p>

<p>Action to be taken if the patient is excluded (continued)</p>	<p>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.</p> <p>Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken.</p>
<p>Action to be taken if the patient or carer declines treatment</p>	<p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. 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'.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p>
<p>Arrangements for referral</p>	<p>As per local policy.</p>

<p>Off-label use (continued)</p>	<p>domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.</p> <p>Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. No specific management is required for individuals with a family history of allergies.</p> <p>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.</p> <p>The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged.</p> <p>Storage</p> <p>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.</p> <p>In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NHS operational guidance or standard operating procedure.</p> <p>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.</p>
<p>Route / method of administration</p> <p>Continued over page</p>	<p>Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine is for administration by intramuscular injection only, preferably into deltoid region of the upper arm.</p> <p>Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine requires dilution in its original vial with 1.8ml of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3ml dose for administration.</p> <p>Vaccine should be prepared in accordance with manufacturer's recommendations (see the product's SPC) and NHS standard operating procedures for the service.</p> <p>Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw.</p> <p>Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use.</p> <p>Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.</p> <p>Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</p> <p>The thawed vaccine must be diluted in its original vial with 1.8ml sodium chloride 0.9% solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</p> <p>Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8ml air into the empty diluent syringe.</p> <p>Gently invert the diluted dispersion 10 times. Do not shake the vaccine.</p> <p>The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.</p> <p>The diluted vials should be marked with the appropriate date and time.</p>

<p>Route / method of administration (continued)</p>	<p>After dilution store at 2°C to 30°C and use within 6 hours, including any transportation time.</p> <p>Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</p> <p>The vaccine dose should be drawn up from the diluted vial immediately prior to administration.</p> <p>In order to extract at least 6 doses from a single vial, low dead-volume syringes and/or needles should be used. Each dose must contain 0.3ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.</p> <p>Discard any unused vaccine within 6 hours after dilution.</p> <p>Check product name, batch number and expiry date prior to administration.</p>
<p>Dose and frequency of administration</p>	<p>A dose of Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine is 0.3ml. Each dose contains 30micrograms of COVID-19 mRNA vaccine in 0.3ml.</p> <p>The 2-dose primary course consists of first dose of 30micrograms in 0.3ml followed, after an interval of at least 21 days, by a second dose of 30micrograms in 0.3ml. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which is set out in Chapter 14a and summarised below and in a table at Appendix A.</p> <p>For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used.</p> <p>Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of 8 weeks between doses of all the available COVID-19 vaccines where a 2-dose primary schedule is used for adults and for children at high risk. Operationally, using the same minimum interval for all products will simplify supply and booking, and will help to ensure a good balance between achieving rapid and long-lasting protection.</p> <p>For those under 18 years who are not in a risk group a 12-week interval is preferred (see below and Appendix A). This is based on precautionary advice from the JCVI based on emerging evidence of a lower rate of myocarditis in countries that use schedules of 8 to 12 weeks. The interval may be shortened to 8 weeks 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 between doses will be advised by JCVI or UKHSA and published in NHSEI operational guidance.</p> <p>The main exception to the 8-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the licensed minimal interval of at least 21 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond.</p> <p>If the primary course is interrupted or delayed, it should be resumed (using the same vaccine as was given for the first dose if possible, see Additional Information) but doses should not be repeated.</p> <p>Interval post COVID-19 infection</p> <p>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.</p>

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<p>Dose and frequency of administration (continued)</p> <p>Continued over page</p>	<p>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).</p> <p>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 NHSEI operational guidance.</p> <p>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.</p> <p>Primary course for individuals in a risk group</p> <p>The primary course for individuals in a risk group is recommended to be scheduled as follows:</p> <ul style="list-style-type: none"> • individuals 12 years and over sharing living accommodation with an immunosuppressed individual of any age should receive a 2-dose primary course at a recommended 8-week minimum interval • individuals 12 years and over in an at-risk group⁴ should receive a 2-dose primary course at a recommended 8-week minimum interval • individuals from 16 years of age who are health and social care workers or carers⁴ should receive a 2-dose primary course at a recommended 8-week minimum interval <p>Third primary dose</p> <p>Individuals 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule should receive a 3-dose primary course (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in those aged 12 years and above' in Chapter 14a). The third dose should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum (see Additional information section).</p> <p>Individuals who are not in a risk group</p> <p>The primary course for individuals who are not in a risk group is recommended to be scheduled as follows:</p> <ul style="list-style-type: none"> • individuals 12 to 17 years of age and not in a risk group (see above) should receive a 2-dose primary course at a recommended 12-week minimum interval⁴. This interval may be reduced to 8 weeks 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 between doses will be advised by JCVI or UKHSA and published in NHSEI operational guidance. • individuals 18 years of age and over and not in a recognised risk group should receive a 2-dose primary course at a recommended 8-week minimum interval
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⁴ At risk groups are listed in [Chapter 14a](#) (Table 3 for individuals 16 years of age and over and Table 4 for children aged 12-15 years).

<p>Dose and frequency of administration (continued)</p>	<p>Booster vaccination</p> <p>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 Chapter 14a.</p> <p>Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters.</p> <p>Boosters should be given at a minimum interval of 3 months from the previous dose.</p> <p>JCVI have advised that the Moderna (50microgram), for those aged 18 years and over, and Pfizer-BioNTech (30microgram) vaccines should be used with equal preference in the COVID-19 booster programme. Both vaccines have been shown to substantially increase antibody levels when offered as a booster dose.</p>
<p>Duration of treatment</p>	<p>See Dose and frequency of administration above.</p>
<p>Quantity to be supplied / administered</p>	<p>Administer 30micrograms in 0.3ml per dose.</p>
<p>Supplies</p>	<p>Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider.</p> <p>NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Comirnaty® 30micrograms/dose COVID-19 mRNA Vaccine, which ensure use is in accordance with product's SPC and official national recommendations.</p>
<p>Storage</p>	<p>Comirnaty® 30micrograms/dose COVID-19 mRNA Vaccine is supplied from the manufacturer as a multiple-dose vial of frozen, preservative-free concentrate, which requires storage at -90°C to -60°C.</p> <p>Frozen Vial</p> <p>Shelf life is 9 months at -90°C to -60°C</p> <p>Within the 9 months shelf life, unopened vials may be stored and transported at -25°C to -15°C for a single period of up to 2 weeks and can be returned to -90°C to -60°C.</p> <p>Thawed vial</p> <p>Thawed unopened vials have a 1-month shelf-life at 2°C to 8°C.</p> <p>Within the 1-month shelf-life at 2°C to 8°C, up to 12 hours may be used for transportation.</p> <p>Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30°C.</p> <p>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. Thawed vials can be handled in room light conditions.</p> <p>Once a vial is removed from the tray, it should be thawed for use.</p> <p>Once thawed the vaccine cannot be re-frozen.</p> <p>Diluted product</p> <p>Chemical and physical in-use stability, including during transportation, has been demonstrated for 6 hours at 2°C to 30°C after dilution in sodium chloride 0.9% solution for injection. From a microbiological point of view, unless the</p>

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<p>Storage (continued)</p>	<p>method of dilution precludes the risk of microbial contamination, the product should be used immediately.</p> <p>Precautions for storage</p> <p>Store in original packaging in order to protect from light.</p> <p>During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.</p> <p>Thawed vials can be handled in room light conditions.</p> <p>These details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The product's SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.</p>
<p>Disposal</p>	<p>Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.</p> <p>Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).</p>
<p>Drug interactions</p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination.</p> <p>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.</p> <p>For further information about co-administration with other vaccines see Additional Information section.</p>
<p>Identification and management of adverse reactions</p> <p>Continue over page</p>	<p>The most frequent adverse reactions in individuals 16 years of age and older are injection site pain, fatigue, headache, myalgia, chills, arthralgia, pyrexia and injection site swelling. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Redness at the injection site, nausea and vomiting are reported as common. Lymphadenopathy is reported with a frequency of less than 1%.</p>

<p>Identification and management of adverse reactions (continued)</p>	<p>The most frequent adverse reactions in individuals 12 to 15 years of age are injection site pain, fatigue, headache, myalgia, chills, arthralgia and pyrexia.</p> <p>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.</p> <p>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.</p> <p>A detailed list of adverse reactions is available in the product's SPC.</p>
<p>Reporting procedure of adverse reactions</p>	<p>Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product.</p> <p>Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.</p> <p>The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.</p>
<p>Written information to be given to patient or carer</p>	<p>Ensure the individual has been provided appropriate written information such as the:</p> <ul style="list-style-type: none"> • Patient Information Leaflet (PIL) for Comirnaty® 30micrograms/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
<p>Patient advice / follow up treatment</p> <p>Continued over page</p>	<p>There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label section).</p> <p>Following COVID-19 vaccine administration, individuals without a history of allergy should be:</p> <ul style="list-style-type: none"> • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the 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) <p>Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5.</p>

<p>Patient advice / follow up treatment (continued)</p>	<p>Inform the individual/parent/carer of possible side effects and their management.</p> <p>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.</p> <p>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.</p> <p>Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.</p> <p>Advise the individual/parent/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme or 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.</p> <p>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.</p> <p>When applicable, advise the individual/parent/carer when to return for vaccination or when a subsequent vaccine dose is due.</p>
<p>Special considerations / additional information</p> <p>Continued over page</p>	<p>Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.</p> <p>Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.</p> <p>Pregnancy</p> <p>Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman.</p> <p>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.</p> <p>Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women.</p> <p>If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval.</p> <p>Breastfeeding</p> <p>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.</p> <p>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.</p> <p>Previous incomplete vaccination</p>

Special considerations / additional information
(continued)

If the course is interrupted or delayed, it should be resumed using the same vaccine if possible but the earlier doses should not be repeated.

Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with heterologous doses are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency ([EMA](#)). For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. In these circumstances, this PGD may be used.

Children aged 12 years who have commenced immunisation with the Comirnaty® 10micrograms dose should complete vaccination with the 10micrograms dose, see [Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine PGD](#), although the 30microgram dose is an alternative. Those who present for the second dose over the age of 12 years should be given the 30microgram dose.

Children aged 12 years who have commenced vaccination with the 30microgram dose and who are being vaccinated alongside their peers from school year 7 may complete the course with the 10microgram dose, see [Comirnaty® 10micrograms/dose COVID-19 mRNA vaccine PGD](#).

For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with the AstraZeneca COVID-19 vaccine, current evidence would support completion of the course with an mRNA vaccine, provided a period of at least 12 weeks has elapsed since the dose of AstraZeneca vaccine.

Individuals with a history of capillary leak syndrome should be carefully counselled about the risks and benefits of vaccination. An alternative vaccine to the AstraZeneca COVID-19 vaccine, such as Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine, may be offered.

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).

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 2 or more vaccines. It is generally better for vaccination to proceed and it may be provided under this PGD, to 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 (including influenza and pneumococcal

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<p>Special considerations / additional information (continued)</p>	<p>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). 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.</p> <p>A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. 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 2 will avoid confusion over systemic side effects.</p> <p>Non-responders / immunosuppressed</p> <p>Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated.</p> <p>JCVI advises that a third primary vaccine dose be offered to individuals aged 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in those aged 12 years and above' in Chapter 14a). Most individuals whose immunosuppression commenced at least 2 weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤ 40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.</p> <p>Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum.</p> <p>Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). This is not covered by this PGD and should be provided on a patient specific basis.</p>
<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • 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

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Records (continued)	<ul style="list-style-type: none">• supplied via PGD <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.</p>
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6. Key references

Key references	<p>Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine</p> <ul style="list-style-type: none">• Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 28 February 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book• UK Chief Medical Officers Report; suspension of the 15minutes wait for vaccination with mRNA vaccine for COVID-19 13 December 2021• Summary or Product Characteristics and Patient Information Leaflet for Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine 14 March 2022. https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19• COVID-19 vaccination programme. Updated 3 March 2022. https://www.gov.uk/government/collections/covid-19-vaccination-programme• Training recommendations for COVID-19 vaccinators. Updated 4 October 2021. 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 16 March 2021 https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool• COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners <p>General</p> <ul style="list-style-type: none">• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-hm-07-01/• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources• Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them• UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/ukxi/2012/1916/contents• UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/ukxi/2020/1125/contents/made• UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/ukxi/2020/1594/regulation/4/made
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7. Practitioner authorisation sheet

Comirnaty® 30micrograms/dose COVID-19 mRNA vaccine PGD v07.00

Valid from: 31 March 2022 Expiry: 1 April 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.

APPENDIX A (Read in conjunction with [Dose and frequency of administration](#) section)

Recommended primary dose schedule by age and risk status.

Individuals who are not in a risk group			
Age	Doses	Advised Minimum Interval⁵	Recommendations
12 to 15 years of age and not in a recognised risk group	2	12 weeks ⁶	A decision on boosting those aged 12-15 years not in a risk group is under consideration by JCVI.
16 and 17 years of age and not in a recognised risk group nor working in health and social care or carers	2	12 weeks ⁶	Boosters should be given at a minimum interval of 3 months from the previous dose.
18 years and over and not in a recognised risk group	2	8 weeks	Boosters should be given at a minimum interval of 3 months from the previous dose.
Primary course for individuals in a risk group			
Age	Doses	Advised Minimum Interval⁷	Recommendations
From 12 years of age and sharing living accommodation with an immunosuppressed individual of any age	2	8 weeks	Boosters should be given at a minimum interval of 3 months from the previous dose.
From 12 years of age and in an at-risk group ⁸	2	8 weeks	Boosters should be given at a minimum interval of 3 months from the previous dose.
From 16 years of age who are health and social care workers or carers	2	8 weeks	Boosters should be given at a minimum interval of 3 months from the previous dose.
From 12 years of age and had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule	3	8 weeks	Boosters should be given at a minimum interval of 3 months from the previous dose.

⁵ 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). This recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required. 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 NHSEI operational guidance.

⁶ The interval may be shortened to 8 weeks when rapid protection is required. When rapid protection is required, any reduction in the recommended interval between doses will be advised by JCVI or UKHSA and published in NHSEI operational guidance.

⁷ 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 recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required. 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 NHSEI operational guidance.

⁸ At risk groups are listed in [Chapter 14a](#) (Table 3 for individuals 16 years of age and over and Table 4 for children aged 5-15 years).