Public Health England

Publications approval reference: C1262

Patient Group Direction for COVID-19 Vaccine Moderna

This Patient Group Direction (PGD) is for the administration of COVID-19 Vaccine Moderna to individuals in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of COVID-19 Vaccine Moderna by registered healthcare practitioners identified in Section 3.

The national COVID-19 vaccination programme may also be provided under national protocol or on a patient specific basis (that is by or on the direction of an appropriate independent prescriber). Supply and administration in these instances are not covered by this PGD.

Reference no:	COVID-19 Vaccine Moderna PGD
Version no:	v01.00
Valid from:	16 April 2021
Review date:	1 October 2021
Expiry date:	31 March 2022

Public Health England (PHE) has developed this PGD for authorisation by NHS England and NHS Improvement to facilitate the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement 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 NHS England and NHS Improvement. 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 NHS England and NHS Improvement and service providers. The final authorised copy of this PGD should be kept by NHS England and NHS Improvement for 8 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a 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 PHE developed COVID-19 vaccine PGDs can be found via:
https://www.gov.uk/government/collections/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

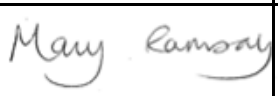
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change history

Version	Change details	Date
V01.00	New PHE PGD template for COVID-19 Vaccine Moderna.	1 April 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, PHE		01/04/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		01/04/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		01/04/2021

In addition to the signatories above the working group included:

Name	Designation
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHS England and NHS Improvement
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHS England and NHS Improvement
Bhavana Reddy	Lead Pharmacy Adviser - Clinical Workstream, Flu and COVID-19 Vaccination Programme, NHS England and NHS Improvement
Gul Root	Principal Pharmaceutical Officer, Department of Health & Social Care and National lead pharmacy public health, Public Health England

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

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team

Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHS England and NHS Improvement completed below.

NHS England and NHS Improvement 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.

NHS England and NHS Improvement 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, NHS England and NHS Improvement	Dr Jonathan Leach OBE		16 Apr 21

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 and UK Summary of Product Characteristics (SPC) and in accordance with official national recommendations.

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can 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 Summary of Product Characteristics (SPC), for the vaccine 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 national NHS standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Mental Capacity Act 2005) and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions

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Additional requirements (continued)	• must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and PHE 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 Public Health England and/or NHS England and NHS Improvement and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

<table>
<tr><td>Clinical condition or situation to which this PGD applies</td><td>COVID-19 Vaccine Moderna 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’, and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.</td></tr>
<tr><td>Criteria for inclusion

Continued over page</td><td>COVID-19 Vaccine Moderna should be offered to individuals, aged 18 years and over, in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance in the following order of priority, starting with those to be vaccinated first:
<table>
<tr><th>Priority</th><th>Risk group</th></tr>
<tr><td>1</td><td>Residents in a care home for older adults and their carers</td></tr>
<tr><td>2</td><td>All those 80 years of age and over
Frontline health and social care workers (see Chapter 14a)</td></tr>
<tr><td>3</td><td>All those 75 years of age and over</td></tr>
<tr><td>4</td><td>All those 70 years of age and over
Clinically extremely vulnerable[2] individuals (see Definition of clinically extremely vulnerable groups)</td></tr>
<tr><td>5</td><td>All those 65 years of age and over</td></tr>
<tr><td>6</td><td>Adults aged 16 years[3] to 65 years in an at-risk group (see the table ‘Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation’ in Chapter 14a)[4]</td></tr>
<tr><td>7</td><td>All those 60 years of age and over</td></tr>
<tr><td>8</td><td>All those 55 years of age and over</td></tr>
<tr><td>9</td><td>All those 50 years of age and over</td></tr>
</table>
Vaccination in pregnancy should be offered, in accordance with Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy (see Cautions).

Phase 2 of the COVID 19 vaccination programme should be offered in accordance with national recommendations and JCVI guidance on the ‘Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme’ in the following age-based order of priority, starting with the oldest adults first and proceeding in the following order:

all those aged 40 to 49 years
all those aged 30 to 39 years
all those aged 18 to 29 years
</td></tr>
</table>

[2] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.
[3] COVID-19 Vaccine Moderna is only authorised for use in those 18 years of age and over (see Criteria for exclusion). COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) may be a suitable alternative for those 16-17 years of age. If COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) is not available a PSD will be required to provide COVID-19 Vaccine Moderna to individuals under 18 years of age.
[4] This also includes adult carers.

Criteria for inclusion continued	Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. The priority order should be followed if it is reasonably practicable to do so. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, such as advised for detained settings[5], where decisions are taken in consultation with national or local public health experts. JCVI advises that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate.[5]
Criteria for exclusion[6]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained. The Patient information leaflet for COVID-19 Vaccine Moderna should be available to inform consent. Individuals who: • are less than 18 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 of the vaccine or residues from the manufacturing process[7] [8] • have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • have history of idiopathic anaphylaxis • 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 28 days • have completed a course of COVID-19 vaccination
Cautions, including any relevant action to be taken Continued over page	All recipients of the COVID-19 Vaccine Moderna should be kept for observation and monitored for a minimum of 15 minutes. Facilities for management of anaphylaxis should be available at all vaccination sites. Where individuals experienced a possible allergic reaction to a first dose of COVID-19 vaccine follow the guidance in Chapter 14a of the Green Book in relation to the administration of subsequent doses. Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting.

[5] https://www.gov.uk/government/publications/letter-from-the-health-and-social-care-secretary-on-covid-19-vaccination-phase-1-advice

[6] 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

[7] Contains polyethylene glycol (PEG), refer to the SPC for COVID-19 Vaccine Moderna for a full list of excipients.

[8] PEG is also an excipient in the COVID-19 mRNA vaccine BNT162b2; individuals who have a systemic allergic reaction to the COVID-19 Vaccine Moderna should not be given a dose of the COVID-19 mRNA vaccine BNT162b2, and vice versa.

Cautions, including any relevant action to be taken (continued)	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. 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. The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see https://www.rcog.org.uk/covid-vaccine). 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/carer should be informed about the risk of haematoma from the injection. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the trial investigators. Eligible individuals who are enrolled in vaccine trials should then be provided with written advice on whether and when they can be safely vaccinated in the routine programme. **Past history of COVID-19 infection** There is no 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 but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. 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.
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Cautions, including any relevant action to be taken (continued)	**Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Administration under this PGD must be in accordance with the most up-to-date advice or amendments (see Chapter 14a and the SPC for COVID-19 Vaccine Moderna).
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. Children at very high risk of exposure and serious outcomes such as older children with severe neuro-disabilities that require residential care should be referred to specialists for consideration for vaccination, under PSD, following assessment of the individual's risk. 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. Special precautions as described in Chapter 14a, and consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with: • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate 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 Such individuals should not be vaccinated with COVID-19 Vaccine Moderna, except on the expert advice of an allergy specialist and under a PSD. The AstraZeneca COVID-19 vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, the AstraZeneca COVID-19 vaccine should be administered in a setting with full resuscitation facilities (such as a hospital) and a 30 minute observation period is recommended. 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 Continued over page	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.

Action to be taken if the patient or carer declines treatment (continued)	Advise the individual/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 for medical advice	As per local policy.

5. Description of treatment

Name, strength & formulation of drug	COVID-19 Vaccine Moderna dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) This is a multidose vial and one vial contains 10 doses. One dose (0.5 ml) contains 100 micrograms of mRNA (embedded in SM-102 lipid nanoparticles).
Legal category	Prescription only medicine (POM).
Black triangle▼	Yes. As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	The COVID-19 Vaccine Moderna SPC recommends that the second dose is administered 28 days after the first dose. For operational purposes, COVID-19 Vaccine Moderna should be administered under this PGD at an interval of 4-12 weeks in accordance with official national recommendations from the JCVI for the delivery of the COVID-19 vaccination programme in England (see Chapter 14a). 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 PHE 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. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Route / method of administration Continued over page	COVID-19 Vaccine Moderna is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccine should be prepared in accordance with the manufacturer's recommendations and NHS standard operating procedures for the service. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. Inspect visually prior to administration and ensure appearance is a white to off-white dispersion. It may contain white or translucent product-related particulates. If foreign particulate matter or discolouration are present, the vaccine should not be administered.

Route / method of administration (continued)	Check product name, batch number and expiry date prior to administration. Swirl the vial gently after thawing and between each withdrawal. Do not shake. Aseptic technique should be used to withdraw each 0.5 ml dose of vaccine from the vial, using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. The dose in the syringe should be used promptly. COVID-19 Vaccine Moderna vials are multidose and, if low dead-volume syringes and/or needles are used, one vial contains at least 10 doses. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials. This product is preservative-free. Once the vial has been used (needle-punctured) to withdraw the initial dose, the vaccine should be used immediately. Any unused vaccine should be discarded after 6 hours.
Dose and frequency of administration	A two-dose course should be administered consisting of 0.5ml followed by a second dose of 0.5ml after an interval of at least 28 days. For operational purposes the second dose may be given between 4 to 12 weeks following the first dose or in accordance with official national guidance at the time. If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible, see Additional Information). The course does not need to be restarted.
Duration of treatment	See Dose and frequency of administration above. Booster doses of COVID-19 vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined.
Quantity to be supplied / administered	Administer 0.5ml per dose. A two-dose course should be completed.
Supplies	Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of COVID-19 Vaccine Moderna, which ensure use is in accordance with the product's SPC and official national recommendations.
Storage Continued over page	COVID-19 Vaccine Moderna multiple-dose vials are stored frozen between -25ºC to -15ºC. Do not store or transport on dry ice or below -40ºC. Protect from light. Shelf life is 7 months at -25ºC to -15ºC. Remove the required number of vials from freezer storage and thaw each vial before use:

Storage (continued)	• thaw in refrigerated conditions between 2°C to 8°C for 2½ hours. Then let each vial stand at room temperature for 15 minutes before administering. • alternatively, thaw at room temperature between 15°C to 25°C for 1 hour. • do not re-freeze vials after thawing. **After thawing** Once thawed, the medicinal product should not be re-frozen and may be stored refrigerated at 2°C to 8°C protected from light for up to 30 days if not used (needle-punctured). Chemical and physical stability of an unopened vial after removal from refrigerated conditions has been demonstrated for 12 hours at 8°C to 25°C. Do not refreeze. **Punctured Vial:** Chemical and physical in-use stability has been demonstrated for 6 hours at 2ºC to 25ºC after first puncture. COVID-19 Vaccine Moderna is preservative-free. Once the vial has been used (needle-punctured) to withdraw the initial dose, the vaccine should be used immediately. Any unused vaccine should be discarded after 6 hours. The above 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. 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 PHE Vaccine Incident Guidance.
Disposal	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 regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions Continued over page	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. It should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Scheduling should ideally be

Drug interactions (continued)	separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines. In most cases vaccination should proceed, and may be provided under the PGD, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. In such circumstances, individuals should be informed about the likely timing of potential adverse events relating to each vaccine.
Identification & management of adverse reactions	The COVID-19 Vaccine Moderna adverse reactions most commonly reported were injection site reactions (including pain, swelling, erythema, urticaria, rash), fatigue, chills, pyrexia, rash, myalgia, arthralgia, headache, nausea, vomiting and lymphadenopathy. Facial paralysis and facial swelling have been rarely reported. Anaphylaxis and hypersensitivity have also been reported. 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. Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/. 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, see https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/ 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 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 for COVID-19 Vaccine Moderna • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding

Patient advice / follow up treatment	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. Nationally recommended protective measures should still be followed. Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Advise the individual/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 on: https://coronavirus-yellowcard.mhra.gov.uk/ . 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. Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see Chapter 14a). When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information Continued over page	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. 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. **Breastfeeding** There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered COVID-19 vaccination. Breastfeeding women may be vaccinated under this PGD. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women. **Previous incomplete vaccination** There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, this PGD may be used and, as COVID-19 vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose.

Special considerations / additional information (continued)	For this reason, until additional information becomes available, further doses would not then be required.
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 Records should be signed and dated (or password-controlled immuniser's record on e-records). 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	COVID-19 Vaccine Moderna • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 12 February 2021. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • COVID-19 vaccination programme. Updated 23 March 2021. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme: advice from the JCVI. Published 26 February 2021. https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi • Definition of clinically extremely vulnerable groups https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev • Training recommendations for COVID-19 vaccinators. Published 08 December 2020. 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. Published 16 March 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Published 26 February 2021. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Summary of product characteristics and patient information leaflet for COVID-19 Vaccine Moderna. Published 1 April 2021. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • 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

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Key references (continued)	• 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 • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made

7. Practitioner authorisation sheet

COVID-19 Vaccine Moderna PGD v01.00 Valid from: 16/04/2021 Expiry: 31/03/2022

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

PGDs do not remove inherent professional obligations or accountability.

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

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

Authorising manager

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

Note to authorising manager

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

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