

PATIENT GROUP DIRECTION (PGD)

Administration of **COVID-19 vaccine** to eligible individuals from the age of 5 years, in accordance with the national COVID-19 vaccination programme.

This Patient Group Direction (PGD) is for the administration of COVID-19 vaccine to eligible individuals from the age of 5 years, in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of COVID-19 vaccine by registered healthcare practitioners identified in [Section 3](#), subject to any limitations to authorisation detailed in [Section 2](#).

The national COVID-19 vaccination programme may also be provided under a vaccine group direction (VGD) 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 (5 years and over) PGD**

Version no: v5.0

Valid from: 1st October 2026

Expiry date: 1st February 2027

The Strategic Planning and Performance Group (SPPG) and the Public Health Agency (PHA) have adapted the UK Health Security Agency's (UKHSA) COVID-19 vaccine (5 years and over) PGD v05.0 (Publications approval reference **2026317**) to facilitate the delivery of the national COVID-19 immunisation programme within Northern Ireland.

Trust staff using this PGD must ensure that it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH [HMR2012 SCHEDULE 16 Part 2](#).**

Primary Care/Trusts must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 'Characteristics of staff'. Only sections 2 and 7 can be amended within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the organisation using the PGD. Section 7 is to be completed by registered practitioners providing the service and their authorising manager.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires². Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

¹ This includes any relevant amendments to legislation

² Department of Health, Good Management, Good Records, [Disposal Schedule - Section G part 2](#), G84.
COVID-19 vaccine (5 years and over) PGD v5.0 Valid from: 01/10/2026 Expiry: 1/02/2027 Page 1 of 29

Individual registered practitioners must be authorised by name, to work according to the current version of this PGD, by signing section 7. A counter signature must also be provided by a manager with the relevant level of authority, by signing [SECTION 7](#). Providers are also reminded to ensure vaccination is in line with the contractual arrangements and any limitations of service provision as well as the criteria for inclusion.

Practitioners and organisations 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 PGD templates can be found on:

- Trust Intranet or
- [Primary Care Intranet](#)

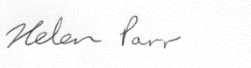
The most current national recommendations should be followed. This may mean a Patient Specific Direction (PSD) is required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

Any concerns regarding the content of this PGD should be addressed to:
pha.immunisation@hscni.net

Change History		
Version number	Change details	Date
V01.00	➤ New SPPG / PHA combined PGD to support delivery of the Autumn 2024 COVID-19 vaccination programme to eligible individuals aged 5 years and over. This PGD reflects the change in antigenic content of the COVID-19 vaccine, from XBB (as utilised in Autumn 2023 and Spring 2024 campaigns) to JN.1. The PGD also amalgamates the 2 previously separate PGDs for adults and children aged 5 to 17 years, into a single legal framework.	16 th September 2024
V2.0	➤ updated to include eligibility criteria for Spring 2025 ➤ updated references and hyperlinks	5 th March 2025
V3.0	updated to include: ➤ eligibility criteria for Autumn 2025 ➤ removed reference to CLS under Cautions section ➤ recommended vaccines for the Autumn 2025 campaign, including the introduction of Comirnaty® LP.8.1 for individuals aged between 5 and 11 years of age and KP.2 30 micrograms for those aged 12 years and over ➤ advice that COVID-19 and RSV vaccines may be co-administered in line with updates to Chapter 27a ➤ replacement of the training recommendations for COVID-19 vaccinators and the COVID-19 vaccinator competency assessment tool, with the national minimum standards and core curriculum for vaccination training ➤ removal of reference to the British Society of Haematology guidance on platelet monitoring in those with a history of idiopathic thrombocytic purpura (ITP), as this has been withdrawn	11 th September 2025
V3.1	Updated to reflect inclusion criteria date of births as per CMO letter include turning 75 by 31 st March 2026	30 th September 2025
V4.0	updated to include: ➤ eligibility criteria for Spring 2026 ➤ recommended vaccines for the Spring 2026 campaign, including the introduction of Spikevax® LP.8.1 for individuals aged 18 years and over, replacement of Comirnaty® KP.2 with Comirnaty® LP.8.1 for individuals aged between 5 and 17 years and Nuvaxovid® JN.1 for individuals from 18 years of age ➤ a switch from vial to prefilled syringe for Comirnaty® 30 micrograms ➤ updated references	18 th March 2026

V5.0	COVID-19 PGD updated to: • recommend vaccines for the Autumn 2026 campaign and subsequent changes to the following sections: 1. name, strength and formulation 2. off-label use 3. route and administration 4. dose and frequency 5. storage 6. Identification and management of adverse reactions 7. written information • add exclusion of individuals aged under 18 years for administration with Bimervax® LP.8. • add exclusion of individuals aged under 12 years Comirnaty® XFG 30 microgram/dose under criteria for exclusion • add exclusion of individuals aged under 18 years for administration with Spikevax 50microgram/dose under criteria for exclusion • amend advice not to drive or use machinery until the prevailing symptoms have cleared instead of 15 minutes after vaccination in the following sections: 1. cautions 2. identification and management of adverse reactions 3. advice and follow up treatment • align the advice for COVID-19 vaccination to the Green Book for individuals who have been diagnosed with Guillain-Barré Syndrome (GBS) after the first dose of COVID-19 vaccine • reorder and clarify the route of administration section • add advice for capillary leak syndrome (CLS) under cautions section • add face swelling in vaccine recipients with a history of injection of dermatological fillers in the adverse reactions section • add in special considerations and additional information section regarding the following: 1. vaccines may not protect all vaccine recipients 2. lag time for full development 3. timing when to vaccinate in individuals with immunosuppression • include rewording, layout and formatting changes for clarity and consistency with other VGD/ PGD templates • update references	14 September 2026
------	---	-------------------

1. PGD template development

Developed by:	Name	Signature	Date
Pharmacist	Helen Parr Pharmacist, SPPG		19/9/26
Doctor	Laura McCartney, Speciality Doctor in Health Protection, PHA		17/9/26
Registered nurse	Zoe Hamilton Health Protection Nurse, PHA		17/9/26

Second Pharmacist Check:

	Name	Date
Pharmacist	Seodhna Gormley Pharmacist, SPPG	21/09/2026

2. Organisational authorisations

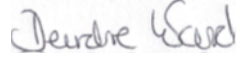
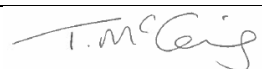
a) Primary Care Authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, contractual arrangements and relevant standard operating procedures (SOPs) for the delivery of the national COVID-19 vaccination programme.

SPPG & PHA authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
HSC Primary Care commissioned immunisation services
Limitations to authorisation

Primary Care approval			
Role	Name	Sign	Date
Consultant in Service Development, PHA	Louise Herron		24/9/26
Pharmacy Lead, Pharmacy and Medicines Management Team, SPPG	Emma Quinn		23/9/26
Strategic Public Health Lead (Starting Well)	Deirdre Ward		22/9/26
Interim Chief Operating Officer, SPPG	Tracey McCaig		24/9/26

GP Practice/ Federation Signatory			
Role	Name	Sign	Date
Lead GP to sign			

[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.

HSC Trust Authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, contractual arrangements and relevant standard operating procedures (SOPs) for the delivery of the national COVID-19 vaccination programme.

INSERT AUTHORISING TRUST NAME authorise this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services e.g. HSC Trusts immunisation services. (Trust to complete)
Limitations to authorisation e.g. Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by ... (Trust to complete).

Organisational approval			
Role	Name	Sign	Date
Trust to enter details here			

Additional signatories according to Trust policy			
Role	Name	Sign	Date

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

3. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccinations where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the sections below. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the Pharmaceutical Society of Northern Ireland (PSNI) • dietitians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC)
Additional requirements (continued over page)	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply and administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of product characteristics (SPC) and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapter of Immunisation Against Infectious Disease (the 'Green Book') • must have undertaken training appropriate to this PGD as required by local policy and SOPs and in line with the National Minimum Standards and core curriculum for vaccination training • where applicable, must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 years of age as required by national or 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 common law in Northern Ireland in relation to the best interests of the incapacitous individual) and to discuss issues related to vaccination. For further information on consent see Reference guide to consent for examination or treatment. • 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 correct technique for drawing up the correct dose • must be competent in the appropriate administration methods for the vaccines listed in this PGD • 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;

Additional requirements (continued)	• must be familiar with Resuscitation Council UK (RCUK) Anaphylaxis guidance for vaccination settings • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and UKHSA COVID-19 vaccination programme: Information for healthcare practitioners • must either 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 policy The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners should be constantly alert to any subsequent recommendations from PHA/SPPG and/or Department of Health (NI) and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	COVID-19 vaccination is indicated for the active immunisation of eligible individuals from the age of 5 years for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. Immunisation is indicated in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page), recommendations given in the COVID-19 chapter of the Green Book, JCVI, and subsequent correspondence/publications from, Department of Health for Northern Ireland (DH(NI)), and Public Health Agency (PHA).
Criteria for inclusion	Individuals who have not already received a dose during the current seasonal campaign and who are: • aged 75 years and over by 31 March 2027 • residents in a care home for older adults; • aged 5 years to 74 years who are immunosuppressed (as defined in the 'immunosuppression' sections of either table 3 or 4 in the COVID-19 chapter of the Green Book) • people in prisons aged 65 years and over, including those due to turn 65 of years on or before 31 March 2027 • included in the recommended cohort(s) for vaccination, if and when JCVI, DH(NI), PHA or other appropriate authority announce an emergency surge vaccine response is required
Criteria for exclusion³ (continued over page)	Individuals for whom valid consent or a 'best-interests' decision in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual has not been received (for further information on consent see Reference guide to consent for examination or treatment). A number of PHA resources are available to inform consent (see Written information to be given to individual, parent or carer section). Individuals who: • are aged under 5 years • are aged under 18 years for administration with Bimervax[®] LP.8.1 (see action to be taken and dose and frequency) • are aged under 18 years for administration with Spikevax[®] XFG 50 micrograms/dose as per JCVI guidance. This is due to the higher reported rates of myocarditis following the vaccine. JCVI continues to advise the use of the Comirnaty[®] vaccine (see Dose and frequency section for full details) • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have already received a dose of COVID-19 vaccine in the last 3 months • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a

³ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required, such as a PSD.

	COVID-19 vaccine or to any component or residue from the manufacturing process⁴ in the COVID-19 vaccines • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe illness (the presence of a minor infection is not a contraindication for vaccination)
Cautions including any relevant action to be taken (continued over page)	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK. The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of allergy (see off-label use section below, CMO letter HSS(MD) 21/2022, and the COVID-19 chapter of the Green Book). Individuals with a personal history of allergy should be managed in line with the COVID-19 chapter of the Green Book Table 5 (management of patients with a history of allergy). Special precautions such as those outlined in the COVID-19 chapter of the Green Book (flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine) are advised for individuals with a personal history of allergy including a: • prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injections, laxatives) • history of idiopathic anaphylaxis Individuals with undiagnosed PEG allergy often have a history of immediate-onset unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Unless at least one dose of the same vaccine has been previously tolerated, it is advisable to seek advice from an allergy specialist (for further information, see the COVID-19 chapter of the Green Book). Rarely, people with PEG allergy may also be allergic to polysorbate 80, which is present in both Bimervax[®] LP.8.1 and the adjuvanted flu vaccines. Individuals who have tolerated the adjuvanted flu vaccine are likely to tolerate a non-mRNA vaccine such as Bimervax[®] LP.8.1. The vaccine should be given in a setting with full resuscitation facilities and the individual should be observed for 30 minutes post administration. Giving Bimervax[®] LP.8.1 in this context is out of scope of this PGD and should be administered under a PSD. Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the COVID-19 chapter 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 a COVID-19

⁴ The Comirnaty[®] vaccines contain polyethylene glycol (PEG); refer to the respective [SPC](#) for a full list of excipients.

Cautions including any relevant action to be taken (continued over page)	vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, particularly in adolescents. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Some of the adverse effects (see SPCs) and syncope may temporarily affect the ability to drive or use machines. It is advised not to drive or use machinery until the prevailing symptoms have cleared. Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in the COVID-19 chapter of the Green Book). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk-benefit is in favour of completing a full COVID-19 vaccination schedule. For individuals with a history of idiopathic thrombocytopaenic purpura (ITP) receiving any COVID-19 vaccine, checking their platelet count should be considered 2 to 5 days post vaccination. Individuals who previously experienced ITP after the first dose of AstraZeneca® vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which COVID-19 vaccine should be considered on an individual basis. A few cases of capillary leak syndrome (CLS) flare-ups have been reported in the first days after vaccination with Spikevax (original). Individuals with a history of capillary leak syndrome, should be carefully counselled about the risks and benefits of vaccination and advice from a specialist should be sought (see the COVID-19 chapter of the Green Book). Past history of COVID-19 infection There are no safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected, asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19. PHA have issued Guidance for vaccination in care homes during COVID / Flu like illness outbreaks. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent
---	---

	deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.
Action to be taken if the individual is excluded (continued over page)	In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. 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. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged. For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 vaccine, or any component of the vaccine, advice should be sought from an allergy specialist and vaccination may be provided by an appropriate prescriber or on a patient specific basis, under a PSD. Where Comirnaty® XFG 30 micrograms/dose mRNA vaccine is not suitable for individuals aged 12 years to 17 years due to allergy to mRNA vaccine, Bimervax® LP.8.1 vaccine can be given following a specialist review and under specialist supervision under a PSD or prescription. Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD (see the COVID-19 chapter of the Green Book for further details). Individuals who have never received a dose of COVID-19 vaccine and do not meet criteria for inclusion, or who were previously eligible for a booster during previous campaigns but not the present one, should be reassured (or their parent or carer) that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk during a future campaign, they will then be invited for vaccination. When the seasonal vaccination campaign has ended, individuals with severe immunosuppression (as defined in Boxes 1 and 2 of the COVID-19 chapter of the Green Book) can be considered for

Action to be taken if the individual is excluded (continued)	vaccination outside of campaign periods, in accordance with the Green Book. A decision to proceed would be subject to individual clinical decision and therefore a PSD should be used to administer the vaccine. If COVID-19 vaccine has been given in the preceding 3 months, advise the individual to return when they are next invited forward for vaccination, which may coincide with the next seasonal vaccine campaign. Document the reason for exclusion and any action taken in the individual's clinical records.
Action to be taken if the individual, parent or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Reference guide to consent for examination or treatment. Advise individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	Seek appropriate advice from the individual's clinician as required.

5. Description of treatment

Name, strength & formulation of drug	Comirnaty® XFG 10 micrograms/dose dispersion for injection, single dose vial COVID-19 mRNA Vaccine Each vial contains a single dose of 0.3ml. One dose of 0.3 mL contains 10 micrograms of mRNA encoding XFG, a COVID-19 mRNA vaccine, (nucleoside modified, embedded in lipid nanoparticles) Comirnaty® XFG 30 micrograms/dose dispersion for injection in pre-filled syringe COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles) Each pre-filled syringe contains a single dose of 0.3ml. One dose of 0.3 mL contains 30 micrograms of mRNA encoding XFG, a COVID-19 mRNA vaccine (nucleoside modified, embedded in lipid nanoparticles) Bimervax® LP.8.1 (40 microgram/dose) emulsion for injection, COVID-19 Vaccine (recombinant, adjuvanted) Each vial contains a single dose of 0.5 ml Each 0.5ml dose contains 40 micrograms of SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion homodimer (Omicron LP.8.1 – LP.8.1 strain) adjuvanted with SQBA. Spikevax® XFG 0.1 mg/mL dispersion for injection Each multidose vial contains 5 doses of 0.5ml. One dose of 0.5 mL contains 50 micrograms of mRNA-1273.262, a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles). Note: For full formulation of the above vaccines see the respective SPCs.
Legal category	Prescription Only Medicine (POM)
Black triangle▼	Yes –all of the above COVID-19 vaccines in use for Autumn 2026 are black triangle products. As new vaccine products, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products.
Off-label use (continued over page)	Allergy The SPCs for all strengths of Comirnaty® COVID-19 mRNA vaccines and Bimervax® LP.8.1 recommend close observation for at least 15 minutes following vaccination. Following careful review of the safety data by the MHRA and advice from the Commission on Human Medicines, the 15-minute observation requirement has since been suspended for individuals who have no history of allergy, following vaccination with all COVID-19 vaccines. Refer to CMO letter HSS(MD) 21/2022 for full information. Individuals (or their parent or carer) should be counselled in line with the relevant points from the advice and follow-up treatment section. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card reporting scheme is strongly encouraged.

Off-label use (continued)	Other off-label uses The Bimervax® LP.8.1 SPC states that individuals who have previously been vaccinated with a COVID-19 vaccine, should be administered Bimervax® at least 6 months after the most recent dose of a COVID-19 vaccine. However, the COVID-19 - Green Book Chapter recommends that it can be given from three months after the previous dose of COVID 19 vaccine. Concomitant administration of Bimervax® LP.8.1 and Comirnaty® XFG 10 micrograms/dose with other vaccines has not been studied. However, they can be co-administered with other vaccines as per the COVID-19 - Green Book chapter. Interchangeability between COVID-19 vaccines The interchangeability of Comirnaty® with COVID-19 vaccines from other manufacturers has not been established, however, the vaccines can be interchanged as per the recommendations in the COVID-19 - Green Book Chapter. Storage Vaccines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Guidance on vaccine handling & storage in GP practices for advice. Where vaccine is assessed following advice by the Medicine Information Service as appropriate for continued use, this would constitute off-label administration under this PGD. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NI operational guidance or standard operating procedure. NICE MPG2 (2017) recommendation 1.1.7 states: <i>‘Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with General Medical Council guidance on prescribing unlicensed medicines.’</i> Where a vaccine is recommended off-label, consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered outside of product licence but in accordance with national guidance
---	---

Route and method of administration (continued over page)	General principles Vaccines should be prepared in accordance with manufacturer's recommendations (see the product's SPC) and standard operating procedures for the service. Vaccines should be inspected for foreign particulate matter and other variation of expected appearance not in line with the product SPC before preparation and administration. Should either occur, discard the vaccine in accordance with local procedures. Vaccines should not be mixed in the same syringe with any other vaccines or medicinal products. Ensure vials (where applicable) are completely thawed prior to use. Unopened vials should be used or discarded by the post-thaw expiry date indicated on the outer packaging. Route of administration The vaccines are given intramuscularly preferably into the deltoid muscle of the upper arm. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. A fine needle (23 gauge or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. Handling of mRNA vials and prefilled syringe • Comirnaty® XFG 10 micrograms/ dose vial • Spikevax® XFG 50 micrograms/ dose vial • Comirnaty® XFG 30 micrograms/dose dispersion for injection in pre-filled syringe Vials Verify that the vial has the correct coloured plastic cap and the label matches the intended vaccine to be administered as outlined in Table 1 below. Do not shake or dilute the vial contents. Thawed vials may be handled in room light conditions. The vial should be marked with the appropriate expiry date and time, once punctured. From a microbiological point of view, the product should be used as soon as practicably possible once opened.
---	---

Route / method of administration
(continued)

Table 1: Summary of vaccine appearance and preparation for:

- Comirnaty® XFG 10 micrograms/dose vial
- Spikevax® XFG 50 micrograms/dose vial and
- Comirnaty® XFG 30 micrograms/dose dispersion for injection in pre-filled syringe prefilled syringe

Vaccine mRNA	Type vial/ prefilled syringe	Vaccine appearance	Vial preparation and prefilled syringe instructions
Comirnaty® XFG 10 micrograms/ dose vial	Blue cap on the vial	Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible.	The vial is received thawed and stored at 2°C to 8°C. The vaccine is ready to use. Gently invert the vial 10 times prior to administration.
Spikevax® XFG 50 micrograms/ dose vial	Blue cap on the vial	White to off-white dispersion	The vial is received thawed and stored at 2°C to 8°C. The vaccine is ready to use Do not shake or dilute. Gently swirl the vial before withdrawing each dose
Comirnaty® XFG 30 micrograms/ dose dispersion for injection in pre-filled syringe	Pre-filled syringe	The dispersion is white to off-white in appearance. Do not dilute prior to use. Do not mix the vaccine in the same syringe with any other vaccines or other medicinal products.	Remove tip cap by slowly turning the cap counterclockwise. Attach a needle appropriate for intramuscular injection and administer the entire volume Do not shake the prefilled syringe

Immediately prior to administration, recheck the product name, batch number, dose volume, post-thaw expiry date (where applicable) and the product expiry date. For Spikevax® check the expiry date and time of any previously punctured vial.

An additional overfill is included in each:

- Spikevax® multidose vial to ensure that 5 doses of 0.5ml can be given. It is advised that the stopper of the Spikevax® vial is pierced at a different site each time a dose is withdrawn. Discard the vial and any excess volume remaining.
- Comirnaty® XFG 10 micrograms/dose single vial dose to ensure that 0.3ml can be given. Withdraw a single 0.3 mL dose of vaccine. Discard the vial and any excess volume remaining.

Route and method of administration
(continued)

To extract the anticipated number of doses from a multidose vial, low dead-volume syringes and/or needles should be used, with a combined dead volume of no more than 35 microlitres.

Handling of non- mRNA vial

Table 2: Summary of vaccine appearance and preparation for:

- Bimervax® LP.8.1 40 micrograms /dose emulsion for injection in a single dose vial

Vaccine Non-mRNA	Vial cap colour	Vaccine appearance	Vial preparation
Bimervax® LP.8.1 40 vial	Blue cap on the vial	Each vial contains a white and homogeneous emulsion Visually inspect the vaccine for particulate matter and/or discolouration prior to administration. Do not administer the vaccine if any of these are present	Immediately prior to use, remove the vaccine vial from the outer carton. Inspect the vial. Gently swirl the vial before the dose withdrawal. Do not shake.

An overfill is included in each vial to ensure that a 0.5 ml dose can be extracted.
Discard any remaining vaccine in the vial after a 0.5 ml dose has been extracted.

Dose and frequency of administration	Vaccination should be offered to individuals eligible for the current campaign, in accordance with the recommendations from the JCVI and in the COVID-19 chapter of the Green Book, at a minimum interval of 3 months from the previous dose of COVID-19 vaccine. In line with the COVID-19 chapter of the Green Book, there is no requirement to administer the same vaccine brand as previously administered. JCVI do not have a preference for a specific COVID-19 vaccine in the adult programme. Children and young people with severe immunosuppression should be offered a Comirnaty® vaccine at a dose appropriate to their age. Table 3: Age specific recommendations on vaccine type and dose regimes <table><tr><th>Age</th><th>Recommended COVID-19 vaccine(s)⁵</th><th>Dose</th></tr><tr><td>5 to 11 years old</td><td>Comirnaty® XFG (10 micrograms/dose)</td><td>0.3ml</td></tr><tr><td>12 to 17 years old</td><td>Comirnaty® XFG (30 micrograms/dose)</td><td>0.3ml</td></tr><tr><td rowspan="2">18 years and over</td><td>Spikevax® XFG (50 micrograms/dose)</td><td>0.5ml</td></tr><tr><td>Bimervax® LP.8.1 (40 micrograms/dose)</td><td>0.5ml</td></tr></table> Where Comirnaty® XFG 30 micrograms/dose mRNA vaccine is not suitable for individuals aged 12 years to 17 years due to allergy to mRNA vaccine, Bimervax® LP.8.1 vaccine can be given following a specialist review and under specialist supervision under a PSD or prescription.	Age	Recommended COVID-19 vaccine(s) ⁵	Dose	5 to 11 years old	Comirnaty® XFG (10 micrograms/dose)	0.3ml	12 to 17 years old	Comirnaty® XFG (30 micrograms/dose)	0.3ml	18 years and over	Spikevax® XFG (50 micrograms/dose)	0.5ml	Bimervax® LP.8.1 (40 micrograms/dose)	0.5ml
Age	Recommended COVID-19 vaccine(s) ⁵	Dose													
5 to 11 years old	Comirnaty® XFG (10 micrograms/dose)	0.3ml													
12 to 17 years old	Comirnaty® XFG (30 micrograms/dose)	0.3ml													
18 years and over	Spikevax® XFG (50 micrograms/dose)	0.5ml													
	Bimervax® LP.8.1 (40 micrograms/dose)	0.5ml													
Duration of treatment	See Dose and frequency of administration above.														
Quantity to be supplied and administered	A single dose, as outlined for the individual’s age in Table 2 .														
Supplies	A central supply of COVID-19 vaccines has been procured. Standard operating procedures should be followed for appropriate storage, handling, preparation, administration and waste minimisation of vaccine, in accordance with product’s SPC and official national recommendations. Further information is also available in the Green Book Chapter 3.														

⁵ As outlined in the Green Book, vaccines that target the latest variant are preferable. However, an available, authorised and age-appropriate vaccine should be offered without delay in preference to a substantial delay to vaccination with a slightly better matched vaccine.

Storage	Table 4: Summary of vaccine handling and storage (thawed vial product)				
	Vaccine product	Transportation time	Product shelf life		
			Thawed vial (unopened)	Punctured vial	Temperature deviations
	Comirnaty® XFG (10 micrograms/ dose)	Up to 10 weeks at 2°C to 8°C (within the 18-month shelf life) Punctured vial: up to 6 hours at 2°C to 30°C	10 weeks at 2°C to 8°C, and 12 hours at 8°C to 30°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
	Spikevax XFG (50 micrograms/ dose)	Up to 36 hours at 2°C to 8°C (up to 30 hours by road and up to 6 hours by air) within the 14 or 30 day thawed shelf life	14 days or 30 days* at 2°C to 8°C as indicated on outer packaging (see Spikevax® storage details)	Up to 6 hours at 2°C to 25°C	Up to 24 hours at 8°C to 25°C
Comirnaty® XFG (10 micrograms/dose dispersion for injection COVID-19 mRNA vial Unopened vials The vaccines will be delivered in thawed state and stored at 2°C to 8°C. The shelf life is up to 10 weeks within the 18-month shelf life for the refrigerated, thawed vials (previously frozen) stored at 2 °C to 8 °C. Store the vaccine in the original package in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed and punctured vials For storage conditions after thawing and first opening see Table 4 above. Spikevax® XFG 50 micrograms/ dose COVID-19 mRNA vial Unopened multidose vial The vaccines will be delivered in thawed state and stored at 2°C to 8°C. Store in the original carton to protect from light. Within the period of 9 months, after removal from the freezer, the unopened vaccine may be stored refrigerated at 2°C to 8°C, protected from light, for a maximum of 30 days. Within this period, up to 36 hours may be used for transportation. Thawed vial When stored for 12 months at -50°C to -15°C, once thawed and stored at 2°C to 8°C and protected from light, the unopened vial has a maximum of 14 days shelf life. This increases to a maximum of 30 days when the vials are removed from the freezer within 9 months. The expiry date on the outer carton should be updated by Movianto to reflect the refrigerated expiry. Thawed vials should not be refrozen. The unopened vaccine may be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.					

Storage (continued)	Transportation of thawed multidose vials in liquid state at 2°C to 8°C Available data support transportation of one or more thawed vials in liquid state for up to 36 hours (maximum of 30 hours by road and up to 6 hours by air) at 2°C to 8°C (within the 30 days or 14 days shelf life, respectively, at 2°C to 8°C). Once thawed and transported in liquid state at 2°C to 8°C, vials should not be refrozen and should be stored at 2°C to 8°C until use. Punctured vial Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 25°C after initial puncture (within the allowed use period of 30 days at 2°C to 8°C and 24 hours at 8°C to 25°C). From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user. Comirnaty® XFG 30 micrograms/dose COVID-19 mRNA in pre-filled syringe Store glass pre-filled syringes at 2 °C to 8 °C (refrigerated only). Do not freeze. Store the vaccine in the original package in order to protect from light. During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet. The shelf life is 12 months when stored at 2 °C to 8 °C. Prior to use, pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C and 30 °C and can be handled in room light conditions. Bimervax® LP.8.1 (40 micrograms /dose) non-mRNA emulsion for injection vial Unopened vaccine should be stored at 2 °C to 8 °C. Do not freeze. Keep the vials in the outer carton in order to protect from light. General advice Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. Refer to standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The product's SPC also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion. Breaches in the cold-chain should be reported in line with local arrangements. Vaccines that have been stored outside of the cold-chain should be quarantined and further advice re use should be sought from the NI Medicines Information Service, see Guidance on vaccine handling and storage in GP practices for contact details. Vaccine losses outside of secondary care should be reported to the PHA Duty Room (telephone 0300 555 0119) for further risk assessment, including whether individuals need revaccination following a cold chain breach.
---------------------------------------	--

Disposal	Follow local clinical waste policy and standard operating procedures to ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste.												
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exist, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. For further information about co-administration with other vaccines see Special considerations and additional Information section. A detailed list of drug interactions associated with each vaccine is available from the product's SPC.												
Identification and management of adverse reactions (continued over page)	The most frequent adverse reactions are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia, and chills. Table 5: Summary of very common adverse reactions for the COVID-19 vaccines <table><tr><th>Vaccine</th><th>Very common</th><th>Common</th></tr><tr><td>Bimervax® LP.8.1</td><td>headache, myalgia, site pain, fatigue</td><td>lymphadenopathy, diarrhoea, vomiting, nausea, injection site swelling, erythema and induration, pyrexia, axillary pain</td></tr><tr><td>Comirnaty® XFG</td><td>irritability, headache, drowsiness, diarrhoea, arthralgia, myalgia, injection site pain, swelling and tenderness, fatigue, chills, pyrexia</td><td>Lymphadenopathy, injection site redness, nausea; vomiting (the frequency category for vomiting was very common in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)</td></tr><tr><td>Spikevax® XFG</td><td>lymphadenopathy, headache, sleepiness, decreased appetite, nausea/vomiting, irritability/crying, injection site pain, fatigue, chills, pyrexia, injection site swelling and erythema, myalgia, arthralgia</td><td>injection site urticaria, injection site rash (can also be a delayed reaction), diarrhoea</td></tr></table>	Vaccine	Very common	Common	Bimervax® LP.8.1	headache, myalgia, site pain, fatigue	lymphadenopathy, diarrhoea, vomiting, nausea, injection site swelling, erythema and induration, pyrexia, axillary pain	Comirnaty® XFG	irritability, headache, drowsiness, diarrhoea, arthralgia, myalgia, injection site pain, swelling and tenderness, fatigue, chills, pyrexia	Lymphadenopathy, injection site redness, nausea; vomiting (the frequency category for vomiting was very common in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)	Spikevax® XFG	lymphadenopathy, headache, sleepiness, decreased appetite, nausea/vomiting, irritability/crying, injection site pain, fatigue, chills, pyrexia, injection site swelling and erythema, myalgia, arthralgia	injection site urticaria, injection site rash (can also be a delayed reaction), diarrhoea
Vaccine	Very common	Common											
Bimervax® LP.8.1	headache, myalgia, site pain, fatigue	lymphadenopathy, diarrhoea, vomiting, nausea, injection site swelling, erythema and induration, pyrexia, axillary pain											
Comirnaty® XFG	irritability, headache, drowsiness, diarrhoea, arthralgia, myalgia, injection site pain, swelling and tenderness, fatigue, chills, pyrexia	Lymphadenopathy, injection site redness, nausea; vomiting (the frequency category for vomiting was very common in pregnant women 18 years of age and older and in immunocompromised individuals 2 to 18 years of age)											
Spikevax® XFG	lymphadenopathy, headache, sleepiness, decreased appetite, nausea/vomiting, irritability/crying, injection site pain, fatigue, chills, pyrexia, injection site swelling and erythema, myalgia, arthralgia	injection site urticaria, injection site rash (can also be a delayed reaction), diarrhoea											

	Very rare cases of myocarditis and pericarditis have been observed following COVID-19 vaccination . The reported rate is highest in individuals under 25 years and in males, usually within a few days following vaccination, after a second dose. Most cases are mild and self-limiting. The MHRA has advised the benefits from vaccination outweigh any risk in most individuals. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Individuals, parents and carers should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as acute and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. Facial swelling in vaccine recipients with a history of injection of dermatological fillers has been reported in the post-marketing phase. Some of the adverse effects (see SPCs) and syncope may temporarily affect the ability to drive or use machines. It is advised not to drive or use machinery until the prevailing symptoms have cleared. Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting. Individuals, parents or carers should be provided with the advice within the leaflet 'What to expect after your child's COVID-19 vaccination (5-11s)' or 'What to expect after your COVID-19 vaccination' as applicable which covers the reporting of adverse reactions and their management, such as with analgesics. A detailed list of adverse reactions across all age groups is available in the product's SPC.
Reporting procedure of adverse reactions	The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals, parents and carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. Chapter 8 and the COVID-19 chapter of the Green Book 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 individual, parent or carer	Ensure the individual, parent or carer has been provided appropriate written information such as the: Patient information leaflets for the administered COVID-19 mRNA vaccine as appropriate: • Comirnaty® XFG (10 micrograms/dose) • Comirnaty® XFG (30 micrograms/dose) • Spikevax® XFG (50 micrograms/dose) • Bimervax® LP.8.1 (40 micrograms/dose) • a guide for parents of children 6 months to 11 years of age at high risk • COVID-19 vaccination - easy read guide • COVID-19 vaccination – guide for people with a weakened immune system • what to expect after your child's COVID-19 vaccination • what to expect after your COVID-19 vaccination Most PHA patient information leaflets are available in multiple languages.

	Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic medicines compendium .
Advice and follow up treatment (continued over page)	Inform the individual, parent or carer of possible side effects and their management. The 15-minute observation following vaccination with COVID-19 vaccines has been suspended for individuals without a history of allergy (see off-label section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the premises • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see Written information to be given to individual, parent or carer section) • where applicable, advise not to drive or use machinery until the prevailing symptoms have cleared. (see Adverse reactions and SPCs) In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Individuals with a personal history of allergy should be managed in line with the COVID-19 chapter of the Green Book, Table 5. No specific management is required for individuals with a family history of allergies. The individual, parent or carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Seek immediate medical attention should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual, parent or carer that they can report side effects directly via the national reporting system run by the MHRA known as the Yellow Card reporting scheme, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that Immunosuppressed individuals may not make a full immune response to the vaccine. When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent dose is due.
Special considerations and additional information	As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection (1mg/ml) and easy access to a telephone at the time of vaccination. As with any vaccine, vaccination with COVID 19 vaccines may not protect all vaccine recipients. Individuals may not be fully protected immediately after their vaccination as there is a lag time for full antibody development (see COVID-19 chapter of the Green Book for further information). 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

(continued over page)

Special considerations and additional information

(continued)

applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring 2 or more vaccines. It is generally better for vaccination to proceed to prevent any further delay in protection and avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings. Examples include LAIV, HPV, influenza, MenACWY and Td-IPV vaccines in the school age programmes, influenza, RSV and pertussis in pregnancy and pneumococcal, shingles and RSV vaccines in those aged over 65 years (for further information see [COVID-19: the green book chapter](#)).

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Where co-administration does occur, the individual, parent or carer should be informed about the likely timing of potential adverse events relating to each vaccine.

Immunosuppressed

The immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. It is expected that vaccines administered during periods of minimum immunosuppression are more likely to generate better immune responses (for further information see [the COVID-19 chapter of the Green Book](#)).

Individuals who had received brief immunosuppression ($\geq 40\text{mg}$ prednisolone per day or [equivalent for children](#)) for an acute episode of asthma and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.

Individuals with severe immunosuppression

Regardless of the time of year or previous vaccination history, additional doses of COVID-19 vaccine may be considered for individuals with severe immunosuppression (as defined by either Box 1 or Box 2: Criteria for additional doses of COVID-19 vaccine, [the COVID-19 chapter of the Green Book](#), as applicable to the individual's age).

The need for additional doses and the optimal dose intervals should be at the discretion of the individual's specialist. In such circumstances, the dose should be given under a PSD or a prescription (see [the COVID-19 chapter of the Green Book](#)).

More information on timing of additional doses may be found in [the COVID-19 chapter of the Green Book](#).

Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment.

Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see [Chapter 7](#) of the Green Book). Revaccination with COVID-19 vaccine is not covered by this PGD and should be provided on a patient-specific basis via a PSD.

Whilst [JCVI do not express a preference](#) for a specific COVID-19 vaccine in the adult population, Comirnaty[®] vaccines are advised for children and young people with severe immunosuppression.

	Pregnancy There is no known risk associated with being given a non-live vaccine during pregnancy when indicated (see Criteria for inclusion and the COVID-19 chapter of the Green Book). Breastfeeding There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that eligible breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19.
Records	Verbally confirm individual's name, address, date of birth, HSC number and Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if the individual is excluded or the individual (or parent or carer) declines immunisation • details of any adverse drug reactions and actions taken • supplied and administered via PGD Records should be signed and dated (or password-controlled on e-records). All records should be clear, legible and contemporaneous. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. For pregnant women, also record immunisation in the hand-held and electronic maternity record if available. The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

6. Key references	COVID-19 vaccines • UKHSA COVID-19 vaccine PGD (5 years and over) v5.0 (with thanks) • CMO Covid letter Autumn 2026. • Summary of Product Characteristics for Comirnaty® XFG 10 micrograms/dose vial PL 53632/0080 14 August 2026 MHRA products and emc • Summary of Product Characteristics for Comirnaty® XFG 30 micrograms/dose pre-filled syringe PL 53632/0078 14 August 2026 MHRA products and emc • Summary of Product Characteristics for Spikevax® XFG 50 micrograms/dose vial PL 53720/0020 27 August 2026 MHRA products and emc • Summary of Product Characteristics Bimervax® LP.8.1 (40 micrograms/dose) vial PL 56346/0006 August 2026 MHRA products • JCVI statement on COVID-19 vaccination in autumn 2026 and spring 2027, 16 July 2025 • UKHSA. The Green Book (Immunisation against Infectious Disease). COVID-19 chapter • COVID-19 vaccination programme. https://www.gov.uk/government/collections/covid-19-vaccination-programme • COVID-19 Vaccination e-learning programme https://www.e-lfh.org.uk/covid-19-vaccination-e-learning-programme-now-live/ • Resuscitation Council UK. Anaphylaxis guidance for vaccination settings https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings • COVID-19 vaccination: information for healthcare practitioners. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Department of Health, NI. HSS(MD)21/2022: Permanent Suspension of the 15-minute wait (13 May 22) https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-21-2022.pdf General • Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste. NHSE. updated 26 January 2024 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 27 March 2017 https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • Reference guide to consent for examination or treatment, Department of Health. Published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition • Guidance on vaccine handling and storage in GP practices. PHA, HSC, DH(NI). Updated August 2024. https://www.publichealth.hscni.net/publications/guidance-vaccine-handling-and-storage-gp-practices
---------------------------------	---

7. Multiple practitioner authorisation sheet

COVID-19 vaccine (5 years and over) PGD v5.0

Valid from: 1st October 2026 Expiry: 1st February 2027

Practitioner

By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability.

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

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

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the 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.

Print extra copies of this page as required. Page ___ of ___