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Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

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National reference: CYM-26003

Local reference: PGD 0252

Patient Group Direction (PGD)

for the administration of

COVID-19 vaccine to

Adults and children aged 5 years and over

by registered healthcare professionals in accordance with the

National COVID-19 Spring Vaccination Programme 2026

in [Powys Teaching Heath Board]

Operational from: 01 April 2026

Review Date: 01 July 2026

Expiry Date: 31 July 2026

Version number: v1.0

PGD for the administration of COVID-19 vaccine to adults and children aged 5 years and over by healthcare professionals in accordance with the National COVID-19 Spring Vaccination Programme 2026

Reference:	COVID-19 vaccine PGD for adults and children aged 5 years and over
Version no:	1.0
Valid from:	01 April 2026
Review date:	01 July 2026
Expiry date:	31 July 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation. 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.

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

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE LISTED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

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.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk.

Change history

Version number	Change details	Date
v1.0	New PGD combining PGDs for 5-11 years old age group and 12 years plus. PGD includes updated advice from JCVI and WHC/2025/052 for the National COVID-19 Spring Vaccination Programme 2026. [Full adoption of WMAS template, addition of PTHB Additional local appendix].	January 2026

[1] This includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178, 2015 No.323 and 2024 No.729).

1. PGD Development

This PGD has been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when a PGD is adopted by an organisation.

PGD Development

Name	Designation	Signature
Expert reviewer – David Andrews	Medical Director for Primary Care and Community, Cwm Taf Morgannwg UHB. Member of the Vaccine Clinical Advisory Group.	
Main author – Nia Sainsbury	Lead Pharmacist Publications. Welsh Medicines Advice Service, Cardiff and Vale UHB.	
Expert reviewer – Hawys Youlden	Lead Nurse/Practitioner VPDP, Health Protection Team, Public Health Wales	

This PGD has been peer reviewed by the Vaccine Clinical Advisory Group in accordance with the WMAS PGD Policy and ratified by the All-Wales PGD Advisory Board.

Expert Panel – Vaccine Clinical Advisory Group

Name	Designation
Andrew Evans	Chief Pharmaceutical Officer
Dianne Burnett	Director. Welsh Medicines Advice Service, Cardiff and Vale UHB
Christopher Johnson	Head of VPDP, Public Health Wales
Beverley Griggs	Consultant in Health Protection/Communicable Disease Control, Public Health Wales
David Andrews	Medical Director representative, Primary Care, Cwm Taf Morgannwg UHB.
Siân Owen	Lead Doctor Immunisation, Associate Specialist in Community Paediatrics, Betsi Cadwaladr UHB
Heather Payne	Senior Medical Officer Welsh Government
Paul Labourne	Senior Nursing Officer, Office of the CNO, Welsh Government
Nicola Bevan	Nurse Consultant, Deputy Head Vaccine Preventable Disease Program Public Health Wales

Date VCAG approval of PGD: 19 March 2026

Date All Wales PGD Advisory Board ratification: 19 March 2026

2. Organisational 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 this PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

[Powys Teaching Health Board] authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Powys Teaching Health Board Powys Teaching Health Board GP Practices: role, organisation, name, signature and date must be added to indicate adoption
Limitations to authorisation
N/A

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	3/25/2026
Head of Community Services Medicines Management / Pharmacy	Jayne Price	DocuSigned by: Jayne Price A9AFDC3B15294CC...	3/25/2026
Clinical Governance Lead for PTHB	Amanda Edwards	Signed by: Lucie Cornish 48844B7FC02A448...	3/27/2026

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**
Executive Director of Nursing and Midwifery for PTHB	Paul Hooton	Signed by: Paul Hooton EEABC83AC83F4B9...	3/25/2026

Local enquiries regarding the use of this PGD may be directed to: [Medicines Management on 01874 712641].

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

Appendix D provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner authorisation sheet as included at the end of this PGD.

Details of local policy or guidance that should be read in conjunction with this PGD
[PTHB Additional local appendix (attached to the end of this PGD]

Retention statement

The final authorised copy of this PGD should be kept by the authorising organisation completing section 2 for 25 years after the PGD expires as the PGD relates to adults and children.

Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

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 use them): ➢ nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). ➢ pharmacy professionals (pharmacists and pharmacy technicians) currently registered with the General Pharmaceutical Council (GPhC). ➢ chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC). ➢ dental hygienists and dental therapists registered with the General Dental Council (GDC). ➢ optometrists registered with the General Optical Council (GOC). Practitioners must also fulfill all the additional requirements. Check section 2 limitations to authorisation to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements (continued over page)	Additionally: ➢ practitioners must be employed by or providing services on behalf of [PTHB or a PTHB GP Practice]. ➢ practitioners must be authorised by name as an approved practitioner under the current terms of this PGD before working to it. ➢ practitioners must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs). ➢ practitioners must be familiar with the vaccine products and alert to changes in the Summary of Product Characteristics (SmPC), Immunisation Against Infectious Disease (the 'Green Book'), and national and local immunisation programmes (the Welsh Health Circulars and Public Health Wales). ➢ practitioners must have undertaken appropriate training for working under PGDs for supply / administration of medicines. ➢ practitioners must have received COVID-19 vaccine training through attending a taught session and/or eLearning. ➢ a COVID-19 vaccination eLearning programme has been written by UKHSA and developed by Health Education England eLearning for Healthcare (eLfH). The programme consists of a Core Knowledge session and an assessment session and vaccine-specific sessions

Additional requirements (continued)	together with accompanying assessments for each of the COVID-19 vaccines currently in use. This eLearning is available to access here: COVID-19 vaccination - Public Health Wales (nhs.wales). ➢ if practitioners are new to immunisation the national minimum standards and core curriculum for vaccination training apply. Practitioners delivering training should adapt the curriculum (the topics covered, and the level of detail required) to the specific needs of the workforce depending on the nature of their role in terms of delivering the COVID-19 vaccine programme. ➢ if a practitioner has not received any vaccine update training in the past year, it is recommended that they also undertake the vaccine administration, storage and handling of vaccines and legal aspects eLearning modules available in the Immunisation programme - Public Health Wales (nhs.wales). This page offers support on how to access these resources via ESR, or for staff outside of NHS Wales via the learning@Wales platform. Training resources and guidance documents are also available to view here: Resources for health and social care professionals - Public Health Wales Immunisation training resources and events - Public Health Wales ➢ all new COVID-19 immunisers should complete a competency assessment, for formal assessment and sign-off of their clinical competency. The competencies required will depend on the individual service area and the role of the immuniser. A competency assessment tool is available here: national minimum standards and core curriculum for vaccination training – Appendix A Vaccinator competency assessment tool workbook. The competency assessment tool is also useful for more experienced immunisers to self-assess and identify if there are any areas where they need to update or further their knowledge and skills. ➢ practitioners must be competent to undertake immunisation and to discuss issues related to immunisation. ➢ practitioners must be competent in the injection technique appropriate for the vaccine (see route/method of administration section). ➢ practitioners must be competent in the handling and storage of vaccines, and management of the cold chain. ➢ practitioners must be competent in the recognition and management of anaphylaxis. ➢ practitioners must have access to the PGD and associated online resources. ➢ practitioners 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.**

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Ongoing training and competency	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 Continuing Professional Development (CPD). ➢ be aware of any updates to relevant national guidelines from Public Health Wales, NHS Wales, Welsh Government Welsh Health Circulars (WHC) and other sources of medicines information. ➢ be aware of any updates made to the product in its SmPC or BNF entries or the relevant chapter(s) of 'the Green Book'. ➢ as registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained. ➢ have demonstrated competence in Basic Life Support skills including resuscitation skills and the management of anaphylaxis. Note: The most current national recommendations should be followed. However, if updated recommendations mean that to vaccinate the individual would be outside the scope of this PGD, the individual should be referred to an appropriate clinician for vaccination.

4. Clinical Condition

Clinical condition or situation to which this PGD applies	**COVID-19 vaccine** is indicated for the immunisation of eligible individuals aged 5 years and over, to prevent COVID-19 caused by the SARS-CoV-2 virus, in accordance with official guidance of the national COVID-19 spring vaccination programme 2026 (WHC/2025/052), and the recommendations given in COVID-19: the green book chapter and subsequent official correspondence or publications.
Inclusion Criteria	COVID-19 vaccine should be offered to: ➢ individuals aged 5 years and over as part of the national COVID-19 vaccination programme, in accordance with: o the official guidance in the national COVID-19 spring vaccination programme 2026 (WHC/2025/052). o recommendations given in COVID-19: the green book chapter. For Spring 2026, individuals (aged 5 years and over) in the following groups are eligible for a single dose of COVID-19 vaccine irrespective of prior COVID-19 immunisation status: ➢ all adults aged 75 years and over on 30th June 2026. ➢ residents in a care home for older adults. ➢ individuals aged 5 years to 74 years **who are immunosuppressed** as defined in tables 3 or 4 in the COVID-19: the green book chapter OR ➢ individuals designated as group 0.3 in Welsh Immunisation System (WIS). The vaccine should be offered around 6 months after the last vaccine dose but for operational flexibility a minimum interval of three months (91 days) between doses is considered appropriate. **Individuals with severe immunosuppression** (individuals identified by their specialist as eligible for additional doses of COVID-19 vaccine and grouped as 0.1 or 0.2 in WIS). Regardless of previous vaccination history, additional doses can be considered for individuals with severe immunosuppression# as defined by Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above COVID-19: the green book chapter. **or** Box 2: Criteria for additional doses of COVID-19 vaccine in children aged 6 months to 11 years COVID-19: the green book chapter. Refer to COVID-19: the green book chapter for more information on the dosing interval for additional doses and immunosuppressed individuals. # including individuals who receive bone marrow transplants or CAR-T therapy as they may have lost immunological memory of previous vaccination.

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Exclusion Criteria[2]	COVID-19 vaccines should not be given: ➢ to individuals for whom no valid consent has been received or a 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see chapter 2 of the green book). The patient information leaflet (PIL) for COVID-19 vaccine should be available to inform consent. ➢ to individuals who are less than 5 years of age. Refer to separate PGD for individuals aged 6 months to 4 years. ➢ to individuals who have received a full dose of a COVID-19 vaccine in the preceding 3 months (91 days) unless revaccination is indicated for example some individuals who are severely immunosuppressed. See actions if excluded section. ➢ to individuals who have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination. ➢ to individuals suffering from acute severe illness (the presence of a minor infection is not a contraindication for immunisation). ➢ to individuals who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to: o a previous dose of a COVID-19 vaccine or o any component (excipient) of the COVID-19 vaccine, e.g. polyethylene glycol (PEG) / polysorbate 80. A very small number of individuals have experienced anaphylaxis when receiving a COVID-19 vaccine. Anyone with a history of allergic reaction to an excipient in the COVID-19 vaccine should not receive that vaccine (except with expert advice), but those with any other allergies (such as a food allergy) – including those with prior anaphylaxis – can have the vaccine (see appendix B and the COVID-19: the green book chapter). Where there is doubt, rather than withholding vaccination, seek appropriate advice or refer. See Cautions section below. Spikevax®▼ LP.8.1 should not be given to: ➢ individuals with a medical history of capillary leak syndrome. ➢ individuals less than 18 years of age. Nuvaxovid®▼ JN.1 should not be given to: ➢ individuals less than 18 years of age. See COVID-19: the green book chapter for latest information / updates.
Cautions (continued over page)	Please refer to the relevant SmPC for full details of special warnings and precautions for use.

[2] Exclusion under this PGD does not necessarily mean the vaccines described in section 5 are contraindicated, but it would be outside the remit of this PGD. Another form of authorisation for administration of the vaccine would be required.

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Cautions (continued)	**Bleeding disorder** Individuals with thrombocytopenia or a bleeding disorder may develop a haematoma at the injection site (see route/method of administration). Individuals with a history of immune thrombocytopenia (ITP) may experience a fall in their platelet count. Monitoring of platelets 2-5 days post COVID-19 vaccination in individuals with a history of ITP should be considered as advised in COVID-19: the green book chapter. **Syncope** 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. **Guillain-Barre Syndrome (GBS)** Guillain-Barre Syndrome (GBS) has been reported rarely after COVID-19 vaccination. 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. Evidence suggests that a prior diagnosis of GBS does not predispose an individual to further episodes of GBS and the balance of risk-benefit is in favour of vaccination. See COVID-19: the green book chapter for further information. **Erythema multiforme (EM)** A number of cases of EM have been reported after COVID-19 vaccination and appear to be consistent with EM minor. Recurrence has been reported after rechallenge. EM is uncommon, benign and self-limiting. A past history of EM is not a contraindication for vaccination. See advice section and COVID-19: the green book chapter for further information. **Allergy** Special precautions are advised for individuals with a personal history of allergy including: ➢ prior non-anaphylactic allergic reaction to COVID-19 vaccine. ➢ history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy). ➢ history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative). ➢ history of idiopathic anaphylaxis. Individuals with undiagnosed PEG allergy often have a history of immediate-onset unexplained anaphylaxis or anaphylaxis to multiple classes of drugs.

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Cautions (continued)	Unless at least one dose of the same vaccine has been previously tolerated, it is advisable to seek advice from an allergy specialist. See appendix B table 5 and COVID-19: the green book chapter for further information on management of these individuals with allergy. Rarely, people with PEG allergy may also be allergic to polysorbate 80, which is present in the adjuvanted flu vaccine. Individuals who have tolerated the adjuvanted flu vaccine are likely to tolerate Nuvaxovid®. **Non-allergic reactions** Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. **Individuals vaccinated overseas or as part of clinical trials** All eligible individuals should be vaccinated irrespective of their previous COVID-19 vaccination history, observing a minimum interval of 3 months (91 days) since any previous dose. Specific advice on vaccination of those who received COVID-19 vaccine overseas is available from COVID-19 vaccination: information for healthcare practitioners - GOV.UK.
Action to be taken if the individual is excluded or individual / parent / guardian / carer declines (continued over page)	➢ Seek appropriate advice from a clinical supervisor in the vaccination centre, Immunisation Coordinator, the local immunisation team or the individual's clinician where appropriate. ➢ Explain the reasons for exclusion and any action taken and document in the individual's record in WIS. ➢ In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. ➢ Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see chapter 2 of the green book. ➢ Where individuals have never received a COVID-19 vaccine and do not meet the inclusion criteria, or have been eligible for a COVID-19 vaccine in previous campaigns, but not the present one, reassure the individual / parent / guardian / carer that the clinical evidence does not currently support vaccination. ➢ Unless additional doses are required (see dose and frequency of administration section), where individuals have had a full dose of COVID-19 vaccine in the preceding 3 months, advise the individual / parent / guardian / carer that they should return on or after a 3-month (91 days) period has passed since the last full vaccine dose. ➢ 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 appropriate clinician. Following advice, any subsequent dose should

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Action to be taken if the individual is excluded or individual / parent / guardian / carer declines (continued)	be provided by an appropriate prescriber or on a patient specific basis, under a Patient Specific Direction (PSD). ➢ Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's subsequent doses should be deferred pending further investigation. Following investigation, any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a Patient Specific Direction (PSD). ➢ If the individual / parent / guardian / carer declines, advise about the protective effects of the vaccine and the consequences of not receiving it. ➢ The risk to the individual of not being immunised should be considered. The indications for COVID-19 vaccination are not exhaustive, and practitioners should consider the risk of coronavirus disease exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself and refer individuals to an appropriate clinician for immunisation or a Patient Specific Direction (PSD) obtained where appropriate. ➢ Document all advice given and the decision reached in WIS.
Arrangements for referral for medical advice	If there is any doubt about the administration of the vaccine or an individual's fitness or suitability to receive the vaccine, an appropriate medical professional should be consulted.

5. Description of treatment

Name, strength & formulation of drug

COVID-19 vaccine recommendations for the spring programme 2026 are set out in the COVID-19: the green book chapter.

Some COVID-19 vaccines are restricted for use in particular age groups. The SmPC for individual products should always be referred to.

Table 1: Age-specific recommendations on vaccine name, strength and formulation

Age group	Vaccine	Setting
5 to 11 years	Pfizer: Comirnaty®▼ LP.8.1 10 micrograms/dose dispersion for injection, single dose vial Each vial contains a single dose of 0.3 mL. One dose (0.3 mL) contains 10 micrograms of mRNA encoding LP.8.1.	Health Board
12 to 17 years	Pfizer: Comirnaty®▼ LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe Each pre-filled syringe contains a single dose of 0.3 mL. One dose (0.3 mL) contains 30 micrograms of mRNA encoding LP.8.1.	Health Board
18 years and over	Sanofi: Nuvaxovid®▼ JN.1 dispersion for injection in pre-filled syringe Each pre-filled syringe contains a single dose of 0.5 mL. One dose (0.5 mL) contains 5 micrograms of Omicron JN.1.	Primary Care/ Health Board
18 years and over*	Moderna: Spikevax®▼ LP.8.1 0.1 mg/mL dispersion for injection Each multidose vial contains 5 doses of 0.5 mL. One dose (0.5 mL) contains 50 micrograms of mRNA-1273.251 encoding the viral spike protein of SARS-CoV-2 (LP.8.1).	Health Board/ Primary Care

*** JVCI advice for spring 2026 recommends Moderna Spikevax®▼ LP.8.1 for adults aged 18 years and over despite being licensed for 6 months of age and over.**

As outlined in the COVID-19: the green book chapter, vaccines that target the latest variant are preferable. However, an available, authorised and age -appropriate vaccine should be offered without delay, particularly to individuals at highest risk.

See appendix C for table of excipients and residues for the vaccine.

Legal category	POM - Prescription Only Medicine.
Black triangle ▼	Yes. Being newer vaccines, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme. This information was accurate at the time of writing. See product SmPC for indication of current black triangle status.
Off-label use (continued over page)	Yes. For individuals about to receive planned immunosuppressive treatment, a minimum interval of 3 weeks between COVID-19 doses may be followed, to enable the vaccine to be given whilst the individual's immune system is better able to respond. Ideally, vaccination should take place 2 weeks before immunosuppressive treatment commences, or 2 weeks after the period of immunosuppression, in addition to time needed for clearance of the therapeutic agent. If not possible, consider vaccination during a treatment holiday or when the degree of immunosuppression is at a minimum. Due consideration must be given to the risk of delaying vaccination against that of delaying treatment. More information on dosing intervals for additional doses and optimal timing of doses may be found in COVID-19: the green book chapter. **Observation period** According to the SmPCs / PILs, it is recommended that all recipients of the COVID-19 vaccines are kept for observation and monitored for a minimum of 15 minutes. **The 15 minute observation period following vaccination with COVID-19 vaccines has been removed for ALL individuals of all ages (except those with a history of non-allergic reaction** (see cautions) **or a severe allergic reaction** (as outlined in COVID-19: the green book chapter advice)**).** Vaccinated individuals should be informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. See cautions section. Where a vaccine is recommended off-label, as part of the consent process, consider informing the individual or their parent / guardian / carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence (off-label). Vaccines should be stored according to the conditions detailed in the storage section in this document. However, in the event of an inadvertent or

Off-label use (continued)	unavoidable deviation of these conditions refer to the UKHSA Vaccine Incident Guidance. Where a vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.
Preparation (continued over page)	See relevant SmPC for the full preparation instructions. The vaccines should be prepared using aseptic non-touch technique to ensure sterility. **Pfizer: Comirnaty®▼ LP.8.1 10 micrograms/dose dispersion for injection, single dose vial** **Thawed vial** Once thawed, the vaccine should not be re-frozen. ➢ Verify that the single dose vial has a **blue** cap. ➢ Gently mix by inverting vial 10 times prior to use. Do not shake. ➢ Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. ➢ After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present. ➢ DO NOT dilute the vaccine. ➢ Withdraw 0.3 mL for one 10 microgram dose of Comirnaty®▼ 10 LP.8.1. ➢ Discard vial and any excess volume. ➢ Thawed vials can be handled in room light conditions. **Pfizer: Comirnaty®▼ LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe** ➢ Do not shake or dilute the vaccine. ➢ The vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present. ➢ Remove tip cap by slowly turning the cap counterclockwise. ➢ Attach a needle (of appropriate size for intramuscular injection) and administer the entire volume. **Sanofi: Nuvaxovid®▼ JN.1 dispersion for injection in pre-filled syringe** ➢ Do not shake or dilute the vaccine. ➢ The vaccine should present as a colourless to slightly yellow, clear to mildly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present. ➢ With tip cap upright, remove tip cap by slowly turning the cap counterclockwise.

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Preparation (continued)	➢ Attach a needle (of appropriate size for intramuscular injection) by twisting in a clockwise direction until the needle fits securely on the syringe. ➢ Administer the entire volume. **Moderna: Spikevax®▼ LP.8.1 0.1 mg/mL dispersion for injection multidose vial** **Thawed vial** Once thawed, the vaccine should not be re-frozen. ➢ Verify that the vial has a **blue** plastic cap. ➢ After thawing and before each withdrawal swirl the vial gently. Do not shake. ➢ DO NOT dilute the vaccine. ➢ After mixing, the vaccine may contain white or translucent product-related particulates. Do not use the vaccine if other particulate matter or discolouration is present. ➢ Record the appropriate date/time on the vial. Discard any unused vaccine 6 hours after first puncture. ➢ Withdraw 0.5 mL for each 50 microgram dose of Spikevax®▼ LP.8.1. ➢ Where possible the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung. ➢ Prior to injection confirm liquid is white to off white in colour in both vial and syringe. ➢ If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and any excess volume. ➢ Do not pool excess vaccine from multiple vials. ➢ Thawed vials and filled syringes can be handled in room light conditions.
Route / method of Administration (continued over page)	➢ Prior to administration inspect visually and ensure appearance is consistent with the description above and in the SmPC and the vaccine dose is: ○ 0.3 mL of Comirnaty®▼ 10 LP.8.1 (10 micrograms per dose) for 5 to 11 years old. ○ 0.3 mL of Comirnaty®▼ 30 LP.8.1 (30 micrograms per dose) for 12 to 17 years old. ○ 0.5 mL of Nuvaxovid®▼ JN.1 (5 micrograms per dose) for 18 years old and over. ○ 0.5 mL of Spikevax®▼ LP.8.1 (50 micrograms per dose) for 18 years old and over. (see preparation section). ➢ COVID-19 vaccines are administered by intramuscular injection, preferably into deltoid muscle of the upper arm.

Route / Method of Administration (continued)	➢ Do not inject the vaccine intravascularly, subcutaneously or intradermally. ➢ 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 is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine 25 mm 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 or their parent / guardian / carer should be informed about the risk of haematoma from the injection. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. **Co-administration:** ➢ COVID-19 vaccination may be given at the same time as other vaccines. ➢ 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 in different limbs. ➢ If given in the same limb, they should be given at least 2.5 cm apart. ➢ The site at which each vaccine was given should be noted in the individual's record in WIS.
Dose and frequency of administration (continued over page)	ONE single dose irrespective of prior COVID-19 vaccination status. In line with COVID-19: the green book chapter, 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 immunosuppression should be offered a Comirnaty® vaccine at a dose appropriate to their age.

Dose and frequency of administration

(continued)

Table 2: Age-specific recommendation on vaccine type and dose regimes

Age group	Vaccine	Dose
5 to 11 years	Pfizer: Comirnaty®▼ LP.8.1 10 micrograms/dose dispersion for injection, single dose vial	0.3 mL (10 micrograms per dose)
12 to 17 years	Pfizer: Comirnaty®▼ LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe	0.3 mL (30 micrograms per dose)
18 years and over	Sanofi: Nuvaxovid®▼ JN.1 dispersion for injection in pre-filled syringe	0.5 mL (5 micrograms per dose)
18 years and over	Moderna: Spikevax®▼ LP.8.1 0.1 mg/mL dispersion for injection	0.5 mL (50 micrograms per dose)

For those eligible for vaccination in the Spring 2026 campaign, a single dose is usually scheduled at around six months from the previous dose. To facilitate operational delivery, administration during the current campaign can take place from three months (91 days) after the previous dose. This interval applies to any dose and regardless of the product given for the previous doses.

Individuals with severe immunosuppression (individuals identified by their specialist as eligible for additional doses of COVID-19 vaccine and grouped as 0.1 or 0.2 in WIS).

Regardless of previous vaccination history additional doses can be considered for individuals with severe immunosuppression[#] as defined by Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above COVID-19: the green book chapter.

or

Box 2: Criteria for additional doses of COVID-19 vaccine in children aged 6 months to 11 years COVID-19: the green book chapter.

Refer to COVID-19: the green book chapter for more information on the dosing interval for additional doses and immunosuppressed individuals.

[#] including individuals who receive bone marrow transplants or CAR-T therapy as they may have lost immunological memory of previous vaccination.

For individuals about to receive planned immunosuppressive treatment, a minimum interval of 3 weeks between COVID-19 doses may be followed, to enable the vaccine to be given whilst the individual's immune system is better able to respond. Ideally, vaccination should take place 2 weeks before immunosuppressive treatment commences, or 2 weeks after the period of immunosuppression, in addition to time needed for clearance of the

(continued over page)

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Dose and frequency of administration (continued)	therapeutic agent. If not possible, consider vaccination during a treatment holiday or when the degree of immunosuppression is at a minimum. Due consideration must be given to the risk of delaying vaccination against that of delaying treatment. More information on dosing intervals for additional doses and optimal timing of doses may be found in COVID-19: the green book chapter.
Duration of treatment	See dose and frequency of administration above.
Quantity to be administered	A single dose as described in Table 2: Age-specific recommendation on vaccine type and dose regimes.
Supplies	➢ The Welsh Government and NHS Wales has procured a central supply of COVID-19 vaccines. ➢ Vaccines for use for the national immunisation programme are provided free of charge. ➢ Local NHS standard operating procedures should be followed for appropriate ordering, storage, handling, recording, preparation, administration and waste minimisation. ➢ Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see storage and transportation section below).
Storage and transportation (continued over page)	Store in original packaging in order to protect from light. Do not freeze. **Table 3: Summary of vaccine handling and storage (thawed vials and pre-filled syringes (PFS))**

Vaccine	Product shelf life		
	Thawed vial (unopened) / PFS	**Punctured vial**	**Temperature deviations**
Comirnaty®▼ 10 LP.8.1	Up to 10 weeks at +2°C to +8°C Up to 12 hours at +8°C to +30°C	Not applicable	Up to 24 hours at +8°C to +30°C
Comirnaty®▼ 30 LP.8.1	Up to 12 months at +2°C to +8°C	Not applicable	Up to 12 hours at +8°C to +30°C
Nuvaxovid®▼ JN.1	Up to 9 months at +2°C to +8°C	Not applicable	Quarantine and risk assess
Spikevax®▼ LP.8.1	Up to 30 days at +2°C to +8°C	Up to 6 hours at +2°C to +25°C	Up to 24 hours at +8°C to +25°C (includes up to 6 hours following first puncture)

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Storage and transportation (continued)	In the event of an inadvertent or unavoidable deviation of these conditions, a vaccine that has been stored outside the conditions stated above (fridge failure / breaches in cold chain) should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to: ➢ storage, distribution and disposal of vaccines: the green book chapter 3, and relevant local vaccine policy or guidance. ➢ UKHSA vaccine incident guidance: responding to vaccine errors. ➢ local Medicines Advice Service for advice. Any loss of vaccines due to expiry date, wastage or fridge failure / breaches in cold chain must be reported following local procedure and documented on WIS, ImmForm and via DatixCymru incident reporting system.
Disposal	➢ Any unused product or waste material should be disposed of in accordance with local requirements. ➢ Equipment used for immunisation, including used vials, or discharged vaccines in a syringe, should be disposed of at the end of a session by sealing in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug Interactions	➢ Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still vaccinate this group. ➢ COVID-19 vaccines are considered inactivated and vaccination can proceed if the individual has recently received one or more inactivated or a live vaccine. The same applies for live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual requires two or more vaccines. ➢ Where co-administration does occur, advise the individual or their parent or guardian or carer about the timing of potential adverse effects relating to each vaccine. ➢ COVID-19 vaccines can be given at the same time as other vaccines, preferably at separate injection sites on different limbs. ➢ Monoclonal antibodies to SARS-CoV-2 are available for the treatment and prophylaxis of COVID-19 infection. Limited evidence suggests that no specific interval is required between receipt of these products and COVID-19 vaccination, or vice versa (see COVID-19: the green book chapter).

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Identification and management of adverse effects	If the individual or the parent / guardian / carer is concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. The most frequent adverse reactions for COVID-19 vaccines are injection-site reactions (pain, redness, swelling, rash, urticaria), fatigue, malaise, headache, fever, chills, muscle and / or joint pain, lymphadenopathy, rash, nausea, vomiting and diarrhoea. For Spikevax®▼ LP.8.1, injection site reactions could be delayed in onset on average 9 to 11 days post vaccination. Duration of the reaction is on average 4 days. **Myocarditis and Pericarditis** There is an increased risk of myocarditis and pericarditis following vaccination in those under 25 years of age, in males and after the second dose. Onset is within a few days after vaccination and most cases are mild and have recovered without sequalae. If an individual develops myocarditis or pericarditis following the first COVID-19 vaccination they should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals or the parent / guardian / carer should also be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. **Anxiety-related reactions** Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions (e.g. dizziness, palpitations, increases in heart rate, alterations in blood pressure, paraesthesia, hypoaesthesia and sweating) may occur in association with the vaccination process itself. Stress-related reactions are temporary and resolve on their own. Advise individuals or their parent / guardian / carer to bring symptoms to the attention of the vaccination provider for evaluation. It is important that precautions are in place to avoid injury from fainting. ➢ Advise the individual or their parent / guardian / carer that they should refrain from driving or operating machinery for 15 minutes after vaccination. **Erythema Multiforme (EM)** Benign and self-limiting cases of EM have been reported uncommonly after COVID-19 vaccination (Moderna and Pfizer mRNA vaccines). Advise the vaccinated individual or the parent / guardian / carer to see the GP if they develop a rash on their hands and / or feet which spreads to the tummy, chest, back or face. See advice section and COVID-19: the green book chapter for further information.

(continued over page)

Identification and management of adverse effects (continued)	**Menstrual disorders** Heavy menstrual bleeding has been reported. Most cases appeared to be non-serious and temporary in nature. Encourage the individual or the parent / guardian / carer to report the side effect via the Yellow Card reporting scheme. A detailed list of adverse reactions across all age groups is available in the SmPC.
Reporting procedure for suspected adverse reactions	Any adverse reaction to the product should be documented in the individual's record in WIS and their GP should be informed. Report ALL suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App store. If an adverse reaction occurs during the immediate post-immunisation observation period, document in the individual's record in WIS. All serious adverse reactions and those considered avoidable should also be reported on the DatixCymru incident reporting system. The COVID-19: the green book chapter and chapter 8 provide further details regarding reporting reactions. Allergic reactions that do not include the clinical features of anaphylactoid or anaphylactic reactions should be reported as 'allergic reaction'.
Written information to be given to the individual or their parent / guardian / carer	➢ Prior to vaccination, provide the individual or their parent / guardian / carer with the leaflet: *Get vaccinated against COVID-19. A guide to COVID-19 vaccination*. Available from COVID-19 vaccination information - Public Health Wales (nhs.wales) and available to order for free from Imiwneiddio / Immunisation (nhs.wales). ➢ Offer the marketing authorisation holder's patient information leaflet (PIL). ➢ If applicable, inform the individual or parent / guardian / 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 the marketing authorisation number, as listed on the product SmPC. ➢ If the individual is pregnant, a patient information leaflet is available to support them in their decision to have vaccinations Beichiogrwydd / Pregnancy (nhs.wales).
Individual / parent / guardian / carer advice and follow up (continued over page)	Inform the individual or their parent / guardian / carer: ➢ a full explanation of risks and benefits in order to obtain informed consent. ➢ that the vaccine cannot cause COVID-19 infection. ➢ that it may take up to 7 days for the vaccine to provide protection against COVID-19 infection. ➢ that immunisation may not provide protection in all individuals and government recommended COVID-19 measures should still be followed. ➢ that the vaccine does not protect against other respiratory viruses that often circulate at the same time.

Individual / parent / guardian or carer advice and follow up (continued)	➢ if the individual has a weakened immune system that they may not make a full immune response to the vaccine. ➢ when the individual can be vaccinated if vaccination is postponed because of illness. ➢ when subsequent doses are due if appropriate. ➢ of common side effects, their management and how to access immediate healthcare advice in the event of displaying any adverse reactions. ➢ that they may experience a mild fever, which is common and usually resolves within 48 hours. Feeling generally unwell, shivery, achy and tired is common and usually resolves within one to two days without treatment but paracetamol can be given if necessary to relieve any of these symptoms. ➢ to seek advice from their doctor, or a pharmacist if common side effects do not spontaneously resolve 3 days after vaccination. ➢ if the individual gets any concerning side effects, including side effects not listed in the leaflet to talk to their doctor or a pharmacist. ➢ to seek medical attention immediately if the individual develops new onset chest pain, shortness of breath or palpitations that feel like the heart is fluttering, racing or pounding. ➢ if the individual experiences heavy menstrual bleeding that is unusual for them, especially after the menopause, to speak to a healthcare professional. ➢ to seek medical advice in the event of a severe adverse reaction. ➢ to seek medical attention if the individual develops a rash on their hands and feet which spreads to the tummy, chest, back or face. ➢ that they can report side effects directly to the Yellow Card reporting scheme. ➢ not to drive for 15 minutes after vaccination as fainting can occur following vaccination. ➢ if the individual has a history of immune thrombocytopenia (ITP) advise the individual to contact their GP or specialist clinician to inform them that they have had a COVID-19 vaccine so a blood test 2 to 5 days following the vaccine can be considered. ➢ there is no routine requirement for observation following COVID-19 vaccine administration but following administration, they will be observed for any immediate reactions whilst receiving any verbal post vaccination information and exiting the centre. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. ➢ that the marketing authorisation holder's PIL can be provided. ➢ for more information go to: Immunisation and Vaccines - Public Health Wales (NHS. Wales). ➢ individuals with a personal history of allergy should be managed as advised in appendix B table 5 (COVID-19: the green book chapter). No specific management is required for individuals with a family history of allergies.

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Special considerations / additional information (continued over page)	The practitioner should have immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. See chapter 8 of the Green Book and advice issued by the Resuscitation Council. An age-appropriate protocol for the management of anaphylaxis and an anaphylaxis pack must always be available. Immediate treatment should include early treatment with: ➢ 5 years: 150 micrograms IM (0.15 mL of 1:1000 or 1 mg/mL adrenaline). ➢ 6 years up to 12 years: 300 micrograms IM (0.3 mL of 1:1000 or 1 mg/mL adrenaline). ➢ 12 years and over: 500 micrograms IM (0.5 mL of 1:1000 or 1 mg/mL adrenaline). ➢ an early call for help. ➢ further IM adrenaline every 5 minutes if required. For children under the age of 16 years, those assessed as Gillick competent can self-consent (for further information on consent see chapter 2 of the green book). **Individuals with a 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, but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness, although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms, whether or not they were tested for COVID-19. During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead, provided the residents are clinically stable and infection control procedures can be maintained (see COVID-19: the green book chapter). 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. **Immunocompromised** Individuals with immunosuppression or taking immunosuppressant medication may have a reduced response to vaccination but they should still be vaccinated. See Additional Doses of Vaccination in the COVID-19: the green book chapter.

Special considerations / additional information (continued)	Individuals who have received brief immunosuppression (≥40 mg prednisolone per day or equivalent for children) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to prevent a response to vaccination. **Pregnancy** To support them with their decision to have vaccinations during pregnancy, a patient information leaflet is available from Beichiogrwydd / Pregnancy (nhs.wales).There is no known risk associated with giving a non-live vaccine during pregnancy. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or the foetus. COVID-19 vaccines can be used during pregnancy. **Breastfeeding** There is no known risk associated with giving non-live vaccines during breastfeeding. The JVCI advises that breastfeeding women may be offered vaccination with COVID-19 if eligible. Chapter 6 of the green book states that currently breastfeeding or being breastfed is not a contraindication to routine immunisations. There is no evidence of risk from vaccinating individuals with inactivated vaccines who are breastfeeding. Breastfeeding can continue after vaccination.
Records (continued over page)	The Welsh Immunisation System (WIS) must be used to capture all COVID-19 vaccination data. Record: ➢ that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the Mental Capacity Act 2005. ➢ how the individual met or did not meet the inclusion or exclusion criteria of the PGD. ➢ date and time of administration. ➢ name of individual, address, date of birth and the GP with whom the individual is registered. ➢ allergies and previous adverse events. ➢ details of vaccine, such as name (and brand, where applicable), form, strength, dose, frequency, quantity, route and site of administration. ➢ batch number and expiry date of vaccine. ➢ name and signature of the health professional administering the medicine (if recording on paper), if recording directly on WIS, name only, signature will be replaced by electronic logging of the user. ➢ information provided to the individual or their parent / guardian / carer including side effects and advice given if excluded or declines.

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Records (continued)	➢ details of any adverse drug reaction and actions taken. ➢ referral arrangements (if any). Records should be signed and dated (or password-controlled immunisers record on e-records). All records should be clear, legible and contemporaneous. All records electronically or otherwise must be kept in accordance with NHS Wales record keeping. See: Records management code of practice for health and social care 2022.

Appendices

Appendix A: *References*

- British National Formulary (BNF) – current edition. Available from: https://bnf.nice.org.uk/ [accessed 04 February 2026]
- Health and Care Professionals Council. Standards of conduct, performance and ethics. Updated 01 September 2024. Available from: https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/ [accessed 04 February 2026]
- Joint Committee on Vaccination and Immunisation (JCVI) statements for COVID-19 vaccination in 2025 and spring 2026. Published 14 November 2024. Available from: https://www.gov.uk/government/publications/covid-19-vaccination-in-2025-and-spring-2026-jcvi-advice/jcvi-statement-on-covid-19-vaccination-in-2025-and-spring-2026 [accessed 04 February 2026]
- Medicines and Healthcare Regulatory Agency (MHRA). Patient group directions: who can use them. Updated 04 December 2017. Available from: https://www.gov.uk [accessed 04 February 2026]
- Mental Capacity Act 2005. Available from: https://www.legislation.gov.uk [accessed 04 February 2026]
- National Institute for Health and Care Excellence (NICE). Patient group directions [MPG2]: Competency framework for health professionals using patient group directions. Updated March 2017. Available from: https://www.nice.org.uk/guidance/mpg2/resources [accessed 04 February 2026]
- NHS 111 Wales Health A-Z. Available from: https://111.wales.nhs.uk [accessed 04 February 2026]
- NHS Wales. Welsh Health Technical Memorandum 07-01 – Safe management of healthcare waste. Published 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/ [accessed 04 February 2026]
- Nursing and Midwifery Council. The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates. 2015. Updated October 2018. Available from: https://www.nmc.org.uk/standards/code/ [accessed 04 February 2026]
- Public Health England. National Minimum Standards and Core Curriculum for Vaccination Training. June 2025. Available from: https://www.gov.uk [accessed 04 February 2026]
- Records management code of practice for health and social care 2022. Updated 02 March 2022. Available from: https://www.gov.wales/managing-health-and-social-care-records-code-practice-2022 [accessed 04 February 2026]
- Resuscitation Council UK. Anaphylaxis guidance for vaccination settings. Updated 10 August 2021. Available from: https://www.resus.org.uk [accessed 04 February 2026]
- Royal Pharmaceutical Society. Professional Guidance on the Safe and Secure Handling of Medicines. Updated 22 January 2024. Available from: https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines [accessed 04 February 2026]
- Summary of Product Characteristics (SmPC). Available from: https://www.medicines.org.uk/emc/ [accessed 23 February 2026]

- UK Health Security Agency (UKHSA). COVID-19 vaccination: information for healthcare practitioners. Published 27 November 2020. Last updated 10 September 2025. Available from: https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners [accessed 04 February 2026]
- UK Health Security Agency (UKHSA). Immunisation against infectious disease. COVID-19: The Green Book Chapter. Published 27 November 2020. Last updated 17 March 2026. Available from: https://www.gov.uk [accessed 19 March 2026]
- UK Health Security Agency (UKHSA). Vaccination of individuals with uncertain or incomplete immunisation status. Published September 2013. Last updated 03 February 2026. Available from: https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status [accessed 04 February 2026]
- UK Health Security Agency. Vaccine Incident Guidance. Updated July 2022. Available from: https://www.gov.uk [accessed 04 February 2026]
- Welsh Government. Health circulars. Available from: https://www.gov.wales/health-circulars [accessed 04 February 2026]
- Yellow Card Reporting. Available from: https://yellowcard.mhra.gov.uk/ [accessed 04 February 2026]

Appendix B: *Management of individuals with allergy*

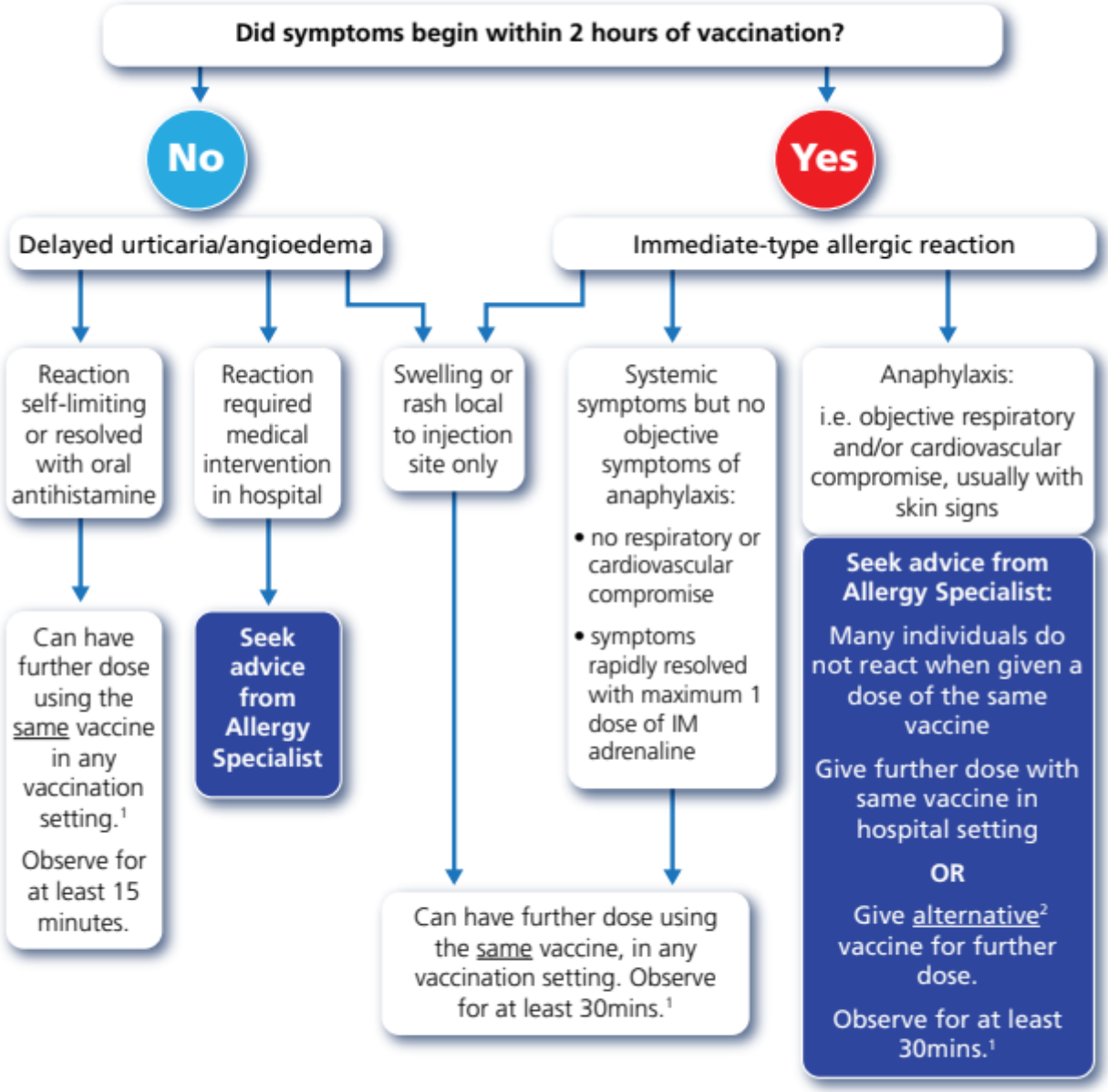
See COVID-19: the green book chapter Table 5: Management of patients with history of allergy.

For individuals with a known PEG allergy, see exclusion criteria.

Table 5: Management of patients with a history of allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• 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 PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pretreatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a person has previously tolerated a dose of the same vaccine, it is safe to administer in any setting. Otherwise - consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to a non-mRNA vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine



1 Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination.

2 If reaction was to AstraZeneca, Novavax or Sanofi Pasteur vaccine, complete or boost with a different vaccine, which may include an mRNA vaccine. If reaction was to an mRNA vaccine, give any mRNA vaccine or Novavax or HIPRA vaccine in a hospital setting.

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Appendix C: *Table to show the excipients for the COVID-19 vaccines*

Vaccine name	Vaccine excipients
Pfizer: Comirnaty®▼ LP.8.1 10 micrograms/dose dispersion for injection, single dose vial	((4-hydroxybutyl) azanediyl) bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide (ALC-0159) (PEG) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Pfizer: Comirnaty®▼ LP.8.1 30 micrograms/dose dispersion for injection in pre-filled syringe	((4-hydroxybutyl) azanediyl) bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (ALC-0315) 2-[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide (ALC-0159) (PEG) 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol Trometamol Trometamol hydrochloride Sucrose Water for injections
Sanofi: Nuvaxovid®▼ JN.1 dispersion for injection in pre-filled syringe	Disodium hydrogen phosphate heptahydrate Sodium dihydrogen phosphate monohydrate Sodium chloride Polysorbate 80 Sodium hydroxide (for adjustment of pH) Hydrochloric acid (for adjustment of pH) Water for injections **Adjuvant (Matrix-M)** Cholesterol Phosphatidylcholine (including all-rac-α-Tocopherol) Potassium dihydrogen phosphate Potassium chloride Disodium hydrogen phosphate dihydrate Sodium chloride Water for injections Adjuvant Matrix-M containing per 0.5 mL dose: Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of *Quillaja saponaria* Molina extract.

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Vaccine name	Vaccine excipients
Moderna: Spikevax®▼ LP.8.1 0.1 mg/mL dispersion for injection	Polyethylene glycol/macrogol (PEG) as part of PEG2000-DMG SM-102 (heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy) hexyl]amino}octanoate) Cholesterol 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG) Trometamol Trometamol hydrochloride Acetic acid Sodium acetate trihydrate Sucrose Water for injections

Appendix D: *Practitioner authorisation sheet*

Patient Group Direction for the administration of COVID-19 vaccine to adults and children 5 years and over v1.0

Valid from: 01 April 2026 Expiry: 31 July 2026

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid. Signed copies of these sheets should be kept in accordance with the retention statement in section 2.

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 [Powys Teaching Health Board] for the above-named health care 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 in accordance with the retention statement in the organisational authorisation section.

Additional appendix for vaccination PGDs, detailing Powys Teaching Health Board (PTHB) PGD requirements

Section of PGD	Additional requirements
Characteristics of staff	Practitioner must have completed Patient Group Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. The practitioner must update at least every 2 years on the administration/use, contra-indications and adverse effects of the medication. Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal development plan** (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Individuals operating under this PGD must be assessed as competent -refer to the practitioner authorisation sheet and the PTHB competency checklist. Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills. Compliance with all mandatory NHS training (if relevant), including safeguarding at the level relevant to the role. Practitioners should be constantly alert to changes in the BNF and Summary of Product Characteristics, and any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and UKHSA and other sources of medicines information. If relevant, HEIW provide training in Wales (CPPE in England). Must have completed: • immunisation training (also see National Minimum Standards and Core Curriculum for Immunisation). Please contact PTHB Immunisation coordinator for further information. • cold chain training (also available via ESR). **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**
Clinical Condition: Situation	**It is the responsibility of the administering/supplying healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding. If there is any reason for concern, seek medical advice.**
Clinical Condition: Inclusion criteria	Medical and drug history taken, no reason for exclusion. PTHB Consent to Treatment and Examination Policy
Clinical Condition: Exclusion criteria	If relevant, other PTHB PGDs may be found using this link Patient Group Directions (PGDs) - Powys Teaching Health Board (nhs.wales).

Cautions	Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list). Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk and • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads
Action to be taken if the individual, parent or carer declines treatment	The patient information leaflet should be available to inform consent. Inform the Child Health department if any vaccination is declined for a child under 19 years, completing the appropriate form. Where appropriate, inform the GP using the local agreed system. If relevant, advise how future immunisation may be accessed if they subsequently decide to receive this.
Description of treatment: Route and method of administration	See Green book chapter 4.
Description of treatment: Storage	Refer to: • MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation Coordinator Powys.Immunisations@wales.nhs.uk, to the Senior Pharmacy Technician for Immunisation/Vaccination Info.MedicinesManagement.Powys@wales.nhs.uk and via PTHB Datix reporting system Once for Wales Reporting System.
Description of treatment: Disposal	Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Description of treatment: Adverse reactions	Report any suspected adverse reactions to a doctor. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO COVID-19 mRNA vaccine** (also state **Brand and Strength**) • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system

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Description of treatment: Written information	Further information for printing and website links suitable for individuals can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources.
Description of treatment: Records	Record consultation details as required by local procedures, to include: • Name of representative who gave consent if appropriate. • Medical and drug history taken, including any allergies and previous adverse events • Printed name and signature of healthcare professional • PGD title and version number If a vaccine is administered to a child up to 19 years of age, forward a notification of vaccination given to Child Health Department using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and Llandrindod Hospital for school age).
Key References	• Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in "comments"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to the individual's line manager and to the staff member, in conjunction with the Practitioner authorisation sheet. A copy of this form should also be kept by service lead in the training file.