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Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

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National reference: CYM-26002

Local reference: PGD 0237E

Patient Group Direction

for the administration of

COVID-19 mRNA vaccine to

Children aged 6 months to 4 years

by registered healthcare professionals in accordance with the

National COVID-19 Spring Vaccination Programme 2026

in [Powys Teaching Health Board]

Operational from: 01 April 2026

Review Date: 01 July 2026

Expiry Date: 31 July 2026

Version number: v5.0

PGD for the administration of COVID-19 mRNA vaccine to children aged 6 months to 4 years by healthcare professionals in accordance with the National COVID-19 Spring Vaccination Programme 2026

Reference:	COVID-19 mRNA vaccine PGD for children aged 6 months to 4 years
Version no:	5.0
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.

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.

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

Change history

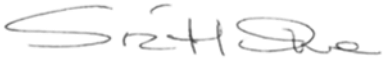
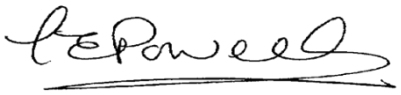
Version number	Change details	Date
v1.0	See previous PGD	21 August 2023
v1.1	See previous PGD	26 February 2024
v2.0	See previous PGD	02 August 2024
v3.0	PGD reviewed and updated with the following changes: • Updated with advice from JCVI and WHC 2024/047 for the Spring Vaccination Programme 2025. • Updated with relevant updates from the SmPCs.	January 2025
v4.0	PGD reviewed and updated with the following changes: • Updated with advice from JCVI and WHC/2025/022 for the National COVID-19 Vaccination Programme Autumn 2025. • Updated with relevant SmPC updates. • Removed Individuals with severe immunosuppression from Off-label use section. • Removed requirement to supply Patient Information Leaflet (PIL) and changed to **offer** PIL. • Addition of Appendix C - Table to show the excipients for the COVID-19mRNA vaccine.	August 2025
v5.0	PGD reviewed and updated with the following changes: • Updated with 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. 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 – Dr Siân Owen	Lead Doctor Immunisation, Betsi Cadwaladr UHB. Member of the Vaccine Clinical Advisory Group	
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 – Clare Powell	Specialist Nurse Immunisation. 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
Christopher Johnson	Head of VPDP, Public Health Wales
Beverley Griggs	Consultant in Health Protection/Communicable Disease Control
David Andrews	Medical Director representative, Medical Director for Primary Care and Community, 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
Dianne Burnett	Director, Welsh Medicines Advice Service, Cardiff and Vale UHB

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 FEABC83AC83F4B9...	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 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 product 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

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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 mRNA vaccine** is indicated for the immunisation of eligible individuals aged 6 months to 4 years, 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/publications.
Inclusion Criteria	COVID-19 mRNA vaccine should be offered to: ➢ individuals aged 6 months to 4 years **who are immunosuppressed** (as defined in table 4 of the COVID-19: the green book chapter and in accordance with the official guidance in the national COVID-19 spring vaccination programme 2026 (WHC/2025/052). **Primary course** The COVID-19: the green book chapter advises that eligible children under 5 years of age should be offered a TWO dose primary course. JCVI advises that any subsequent seasonal doses should be offered at least 3 months (91 days) after the previous dose. **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 (Welsh Immunisation System). Regardless of previous vaccination history, additional doses can be considered for individuals with severe immunosuppression# as defined by 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.
Exclusion Criteria[2] (continued over page)	COVID-19 mRNA vaccine should not be given: ➢ to individuals for whom no valid consent has been received (for further information on consent see chapter 2 of the green book). The patient information leaflet (PIL) for COVID-19 mRNA vaccine should be available to inform consent. ➢ to individuals who are less than 6 months of age. ➢ to individuals aged 5 years and over. Refer to relevant PGD / Vaccine Group Direction (VGD) for 5 years and over.

[2] Exclusion under this PGD does not necessarily mean the vaccine described in section 5 is 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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Exclusion Criteria (continued)	➢ to individuals who have already received a dose in the preceding 3 months (91 days) unless revaccination is indicated, for example some individuals who are 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 mRNA vaccine, e.g. polyethylene glycol (PEG). 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 for the latest information/updates). Where there is doubt, rather than withholding vaccination, seek appropriate advice or refer, see cautions section below.
Cautions (continued over page)	Please refer to the SmPC for full details of special warnings and precautions for use. **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. 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 mRNA vaccination. Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other

Cautions (continued)	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. 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. **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.

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Action to be taken if the individual is excluded or parent / guardian / carer declines	➢ Seek appropriate advice from a clinical supervisor in a 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 on WIS. ➢ In case of postponement due to acute illness, advise the parent / guardian / carer when the child can be vaccinated and ensure another appointment is arranged. ➢ Informed consent, from the person legally able to act on the person's behalf, must be obtained for each administration. For further information on consent see chapter 2 of the green book. ➢ 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 child's parent / guardian / carer that they should return on or after a 3-month (91 days) period has passed since the last full vaccine dose. ➢ 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 child's parent / guardian / carer that the clinical evidence does not currently support vaccination. ➢ For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an appropriate clinician. Following advice, any subsequent dose should 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 second or subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. ➢ If the parent / guardian / carer of the individual 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 mRNA vaccine recommendations for Wales 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. Comirnaty®▼ LP.8.1 3 micrograms / dose concentrate for dispersion for injection 3 dose vial, COVID-19 mRNA vaccine This is a multidose vial with a yellow cap. When thawed, the dispersion may contain white to off white opaque amorphous particles. **Dilute before use**. One vial (1.58 mL) contains THREE doses of 0.3 mL AFTER DILUTION. One dose (0.3 mL) contains 3 micrograms of mRNA encoding LP.8.1. The diluted vaccine is a clear to slightly opalescent dispersion. Vials labelled: **Comirnaty LP.8.1 3 mcg sterile concentrate COVID-19 mRNA Vaccine, 3 doses of 0.3 mL after dilution**. See appendix C for table of excipients 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. The SmPC for Comirnaty®▼ (THREE) LP.8.1 recommends individuals aged 6 months to 4 years have 3 doses as a primary course, the second dose 3 weeks after the first and the third dose at least 8 weeks after the second. The JCVI advises that eligible children aged 6 months to 4 years who are immunosuppressed (as defined in table 4 of the COVID-19: the green book chapter) should receive TWO doses of Comirnaty®▼ (THREE) LP.8.1 given at an interval of 3 months (91 days). 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

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Off-label use (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. **Observation period** According to the SmPC, it is recommended that all recipients of the Comirnaty®▼ (THREE) LP.8.1 vaccine are kept for observation and monitored for a minimum of 15 minutes. **The 15 minute observation period following vaccination with COVID-19 mRNA 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 and appendix B)**).** The child's parent / guardian / carer should be informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of the vaccinated individual 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 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 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 SmPC for the full preparation instructions. Comirnaty®▼ LP.8.1 3 micrograms / dose concentrate for dispersion for injection 3 dose vial, COVID-19 mRNA vaccine **Thawed vial** The vaccine has a maximum shelf life of up to **10 weeks** storage and transportation at +2°C to +8°C (not exceeding the printed expiry date on the outer carton). Upon moving the product to +2°C to +8°C storage, the updated expiry date is written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date on the outer carton should be crossed out.

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Preparation (continued)	Once thawed, the vaccine should not be re-frozen. ➢ Verify that the vial has a **yellow** plastic cap. ➢ Allow the thawed vial to come to room temperature prior to use and gently invert it 10 times prior to dilution. Do not shake. ➢ Comirnaty®▼ (THREE) LP.8.1 should be prepared by a healthcare professional using aseptic technique. Cleanse the vial stopper with a single-use antiseptic swab. ➢ Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles. ➢ Dilute the vaccine in its original vial with 1.1 mL sodium chloride 0.9% solution for injection using a 21 gauge or narrower needle and aseptic technique. ➢ Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.1 mL air into the empty diluent syringe. ➢ Gently invert the diluted dispersion 10 times prior to use. Do not shake. ➢ After dilution, 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. ➢ Record the appropriate discard date/time on the vial. ➢ After dilution, store at +2ºC to +30ºC and use within 12 hours. ➢ If refrigerated allow the diluted dispersion to come to room temperature prior to use. ➢ Do not freeze or shake the diluted dispersion. ➢ After dilution the vial contains 1.58 mL from which 3 doses of 0.3 mL can be withdrawn. ➢ Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. ➢ Withdraw 0.3 mL for each 3 microgram dose of Comirnaty®▼(THREE) 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. ➢ If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. ➢ Do not pool excess vaccine from multiple vials. ➢ Thawed vials 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 (see preparation section). ➢ COVID-19 mRNA vaccines are administered by intramuscular injection. ➢ Administer by intramuscular injection, preferably into the anterolateral aspect of the thigh in infants under one year of age. The deltoid muscle of the upper arm may be used in individuals over one year of age.

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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 child's 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 mRNA 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)	**Vaccination in incompletely and previously unvaccinated individuals** Comirnaty®▼ (THREE) LP.8.1 **Dose: 0.3 mL** TWO doses of 0.3 mL can be used for primary vaccination with a minimum interval of 3 months (91 days) between doses. If the primary course was interrupted or delayed before the Spring 2026 campaign, the course should be resumed and not repeated. JCVI advice recommends TWO primary doses given with an interval of at least 3 months (91 days) for children under 5 years of age. See advice in the COVID-19: the green book chapter. **Previously vaccinated individuals** Comirnaty®▼ (THREE) LP.8.1 **Dose: 0.3 mL**

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Dose and frequency of administration (continued)	ONE single 0.3 mL dose irrespective of the vaccine used for the primary course. See advice in the COVID-19: the green book chapter. 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, vaccination can take place from three months (91 days) after the previous dose. This interval applies 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 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 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	See dose and frequency of administration above.

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Supplies	➢ The Welsh Government and NHS Wales has procured a central supply of COVID-19 vaccine. ➢ 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	Store in original packaging in order to protect from light. Do not freeze. **Thawed vial** The vaccine has a maximum shelf life of up to 10 weeks storage and transportation at +2°C to +8°C (not exceeding the printed expiry date on the outer carton). Upon moving the product to +2°C to +8°C storage, the updated expiry date is written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date on the outer carton should be crossed out. 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, ampoules, 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 vaccines 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 child's parent / guardian / 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).
Identification and management of adverse effects (continued over page)	If the parent / guardian / carer is concerned about their child's health at any time, they should seek advice from their GP or NHS 111 Wales. Safety data of Comirnaty (THREE) LP.8.1 is inferred from safety data of the prior Comirnaty vaccines. Adverse effects reported as very common (more than 1 in 10 people) or common (affecting between 1 in 10 people and 1 in 100 people) include: ➢ headache, irritability, drowsiness. ➢ diarrhoea, nausea, vomiting. ➢ muscle and / or joint pain. ➢ enlarged lymph nodes. ➢ tiredness, chills and fever. ➢ injection site pain, redness and swelling. Adverse effects reported as uncommon (affecting between 1 in 100 and 1 in 1000 people): ➢ dizziness, insomnia. ➢ decreased appetite.

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Identification and management of adverse effects (continued)	➢ pain in the vaccinated arm. ➢ malaise, feeling weak. ➢ allergic reactions such as rash and/or itching (including itching at the injection site). ➢ excessive sweating, night sweats. The most frequent adverse reactions in infants 6 to 23 months of age include irritability, drowsiness, decreased appetite, tenderness at the injection site, injection site redness and fever. **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. Limited data indicate that the risk of myocarditis and pericarditis after vaccination with an age-appropriate dose of Comirnaty vaccine in children aged 5 to 11 years is lower than in ages 12 to 17 years and that in children from 6 months to 4 years of age the risk is similar to, or lower than, that in 5 to 11-year-olds. 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. Advise the child's parent / guardian / carer to seek immediate medical attention should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. **Erythema Multiforme (EM)** Benign and self-limiting cases of EM have been reported uncommonly after COVID-19 mRNA vaccination. Advise the child's 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. A detailed list of adverse reactions is available in the SmPC.
Reporting procedure for suspected adverse reactions (continued over page)	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.

Reporting procedure for suspected adverse reactions (continued)	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 individual or their parent / guardian / carer	➢ Offer the marketing authorisation holder's patient information leaflet (PIL). ➢ Prior to vaccination, provide the child's 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), available to order free from Imiwneiddio / Immunisation (nhs.wales). ➢ If applicable, inform the child's 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 marketing authorisation number, as listed on the product SmPC.
Individual, parent, guardian or carer advice/ follow up (continued over page)	Inform the child's parent / guardian / carer: ➢ a full explanation of risks and benefits in order to obtain informed consent. ➢ of any possible side effects and their management. ➢ that the child 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. ➢ 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. ➢ as the child has a weakened immune system they may not make a full immune response to the vaccine. ➢ when the child can be vaccinated if vaccination is postponed because of illness. ➢ when subsequent doses are due if appropriate. ➢ if the child gets any side effects, including side effects not listed in the leaflet to talk to their doctor or a pharmacist. ➢ to seek medical attention if the child develops a rash on their hands and feet which spreads to the tummy, chest, back or face. ➢ to seek medical attention immediately if the child develops new onset chest pain, shortness of breath or palpitations that feel like the heart is fluttering, racing or pounding.

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Individual, parent, guardian or carer advice/ follow up (continued)	➢ if the child has a history of immune thrombocytopenia (ITP), advise the parent / guardian / carer to contact the child's 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. ➢ to seek medical advice in the event of a severe adverse reaction. ➢ to seek advice from their doctor, or a pharmacist if common side effects do not spontaneously resolve within 3 days of vaccination. ➢ that they can report side effects directly to the Yellow Card reporting scheme. ➢ 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. ➢ that the marketing authorisation holder's PIL can be provided. ➢ for more information go to: Immunisation and Vaccines - Public Health Wales (NHS. Wales). ➢ how to access immediate healthcare advice in the event of the child displaying any adverse reactions. 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 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.
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: ➢ 6 months to 6 years: 150 micrograms IM (0.15 mL of 1:1000 or 1 mg/mL adrenaline. ➢ an early call for help. ➢ further IM adrenaline every 5 minutes if required. **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. Individuals who have received brief immunosuppression (≥2 mg/kg prednisolone per day) for an acute episode of asthma and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to prevent a response to vaccination.

Special considerations / additional information (continued)	**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 (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 are tested for COVID-19. 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 child's underlying condition to the vaccine.
Records	The Welsh Immunisation System (WIS) must be used to capture all COVID-19 vaccination data. Record: ➢ that valid informed consent was given. ➢ 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 and diluent, 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 parent / guardian / carer (including side effects and advice given if excluded or declines). ➢ 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.

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Appendices

Appendix A: *References*

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Appendix B: *Management of individuals with allergy*

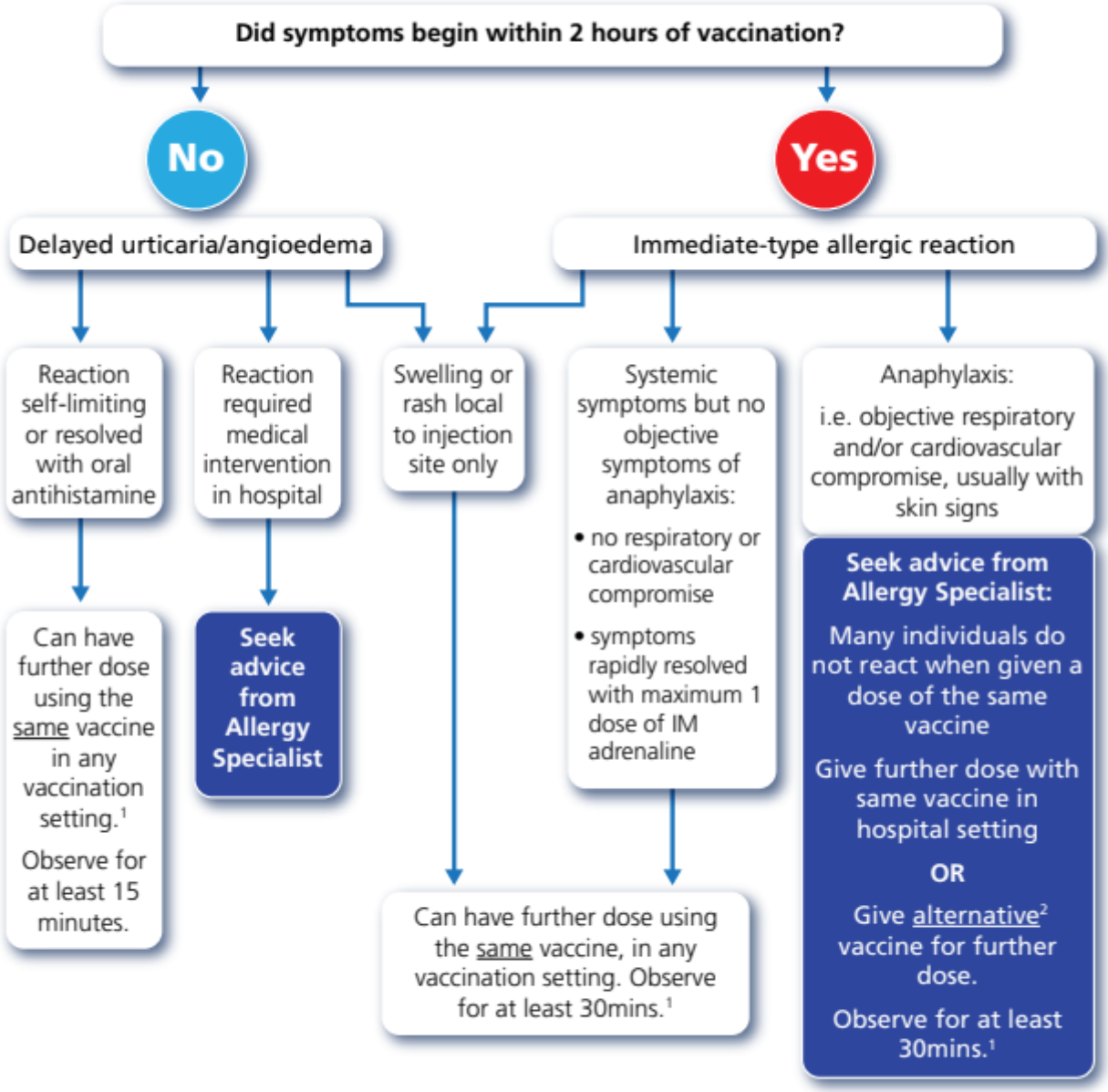
See COVID-19: the green book chapter Table 5: Management of patients with a history of allergy.

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.

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

Vaccine name	Vaccine excipients
Comirnaty®▼ LP.8.1 3 micrograms / dose concentrate for dispersion for injection 3 dose vial, COVID-19 mRNA vaccine	((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

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Appendix D: *Practitioner authorisation sheet*

Patient Group Direction for the administration of COVID-19 mRNA vaccine to children aged 6 months to 4 years v5.0

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

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/

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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.