Public Health Scotland

Administration of COVID-19 mRNA vaccines to individuals aged under 18 years

Patient group direction (PGD) template

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Version 7.0

Translations and other formats are available on request at:

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Most recent changes

Version	Date	Summary of changes
7.0	24 March 2026	The following changes to version 6.0 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Updated throughout with vaccines recommended for use in the Spring 2026 programme. • Action if excluded updated to include reference to Nuvaxovid PGD where mRNA products are considered not clinically suitable for individuals over the age of 12 years. • Advice to patient or carer section updated. • References updated throughout.

Contents

Authorisation

PGD for administration of COVID-19 mRNA vaccines to individuals aged under 18 years

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The registered health professionals who may administer COVID-19 mRNA vaccines to individuals aged under 18 years can only use this PGD as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD. NHS Board governance arrangements should indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine must be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow and Clyde by:

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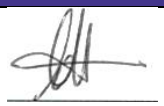
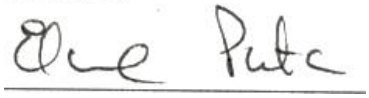
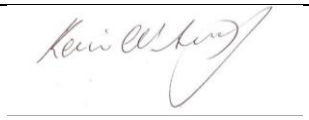
Chair	Dr Craig Harrow	
Director of Pharmacy representative	Elaine Paton, Senior Prescribing Adviser	
Director of Nursing Representative	Kevin McAuley, Chief Nurse North Sector	

Date approved: 30th March 2026

Valid from: 1 April 2026 Expiry date: 31 August 2026

1. Clinical situation

1.1. Indication

COVID-19 mRNA vaccines are indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in those aged under 18 years in accordance with Scottish Government COVID-19 immunisation programme and JCVI advice/recommendations as set out in **The Green Book COVID-19 Chapter** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

COVID-19 mRNA vaccines should be offered to individuals aged under 18 years invited, or eligible in accordance with the recommendations in **The Green Book COVID-19 Chapter**, and/or in line with subsequent correspondence/publications from **Scottish Government**.

Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment schedule.**

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a confirmed anaphylactic reaction to a previous dose of a mRNA COVID-19 vaccine.
- have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture, these include polyethylene glycol (PEG). Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed.
- have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed.
- have a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed.
- have evidence of current deterioration of COVID-19 symptoms: deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).
- are bone marrow and peripheral blood stem cell donors who have commenced Granulocyte-colony stimulating factor (GCSF): the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is precautionary advice to avoid vaccination when receiving GCSF and allow for post-donation recovery period.
- have developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination.
- are aged under six months of age.

Some COVID-19 vaccines are restricted to use in particular age groups.

Practitioners must be familiar with and refer to the marketing authorisation holder's SmPC for the particular vaccine.

- Comirnaty LP.8.1 30 micrograms/dose COVID-19 mRNA vaccine is recommended for those aged 12 to17 years.
- Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine is recommended for those aged 5 to 11 years.
- Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine is recommended for those aged 6 months to 4 years.

1.4. Cautions/need for further advice/circumstances when further advice should be sought from a doctor

The Green Book advises that there are very few individuals who cannot receive COVID-19 vaccines. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

Individuals with a history of allergy

Those with a personal history of allergy should be managed in line with table 5, **The Green Book COVID-19 Chapter**.

Where individuals have experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the flowchart in **The Green Book COVID-19 Chapter** in relation to administration of subsequent doses.

The Green Book COVID-19 Chapter states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended.

No specific management is required for individuals with a family history of allergies.

Individuals with thrombocytopenia

Guidance produced by the UK ITP Forum Working Party advises discussing the potential for a fall in platelet count in patients with a history of immune thrombocytopenia (ITP) receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after vaccination.

Guillain-Barré syndrome (GBS)

Very rare reports have been received of GBS following COVID-19 vaccination. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered.

Individuals with a bleeding history

Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).

Co-administration with other vaccines

The COVID-19 vaccines in use in the UK are considered inactivated: where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes, but is not limited to, vaccines commonly administered around the same time or in the same settings (including inactivated influenza vaccine, pneumococcal vaccines, LAIV, HPV, MenACWY and Td-IPV vaccines in children and young people).

Pregnant woman who are eligible for COVID-19 vaccination can safely have Abrysvo® co-administered with influenza vaccine, COVID-19 vaccine and/or anti-D immunoglobulin.

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 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Syncope

Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Pregnancy and breastfeeding

There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breastfeeding. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or the fetus.

Vaccination should be offered for eligible pregnant women in accordance with recommendations in **The Green Book COVID-19 Chapter**, following a discussion of the risks and benefits of vaccination with the woman.

There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19.

Individuals vaccinated overseas or as part of clinical trials

Individuals who have been vaccinated abroad or in clinical trials are likely to have received a vaccine based on the spike protein or an inactivated whole viral vaccine. These individuals are expected to be boosted by the vaccines currently used in the UK. Specific advice on vaccination of those who received COVID-19 vaccine overseas is available from **UKHSA**.

Individuals with a past history of COVID-19 infection

There are no safety concerns from vaccinating with a past history of COVID-19 infection, or with detectable COVID-19 antibody.

Vaccination of individuals who may be infected or 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.

1.5 Action if excluded

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account.

Where mRNA products are considered not clinically suitable for an individual from the age of 12 to 17 years, vaccination with Sanofi Nuvaxovid JN.1 may be considered. Please refer to Administration of Nuvaxovid JN.1 (Sanofi COVID-19 Vaccine (recombinant, adjuvanted)) Vaccine PGD.

Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

Temporary exclusion

In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.

In case of deferral due to COVID-19 symptoms advise when the individual can be vaccinated and how future vaccination may be accessed.

1.6. Action if patient declines

Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications of disease.

Advise how future immunisation may be accessed if they subsequently decide to receive the vaccine.

Document advice given and decision reached.

Inform or refer to the clinician in charge.

2. Description of treatment

2.1. Name of medicine/form/strength

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles). Single dose, prefilled syringe (0.3ml) contains 30 micrograms of mRNA encoding LP.8.1.

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles). Single dose vial (0.3 ml) contains 10 micrograms of mRNA encoding LP.8.1.

Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles). A multidose vial which **must** be diluted with 1.1ml of 0.9% sodium chloride before use. After dilution each vial contains 3 doses of 0.3 ml. One dose (0.3 ml) contains 3 micrograms of mRNA encoding LP.8.1.

2.2. Route of administration

COVID-19 vaccines must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. For small infants the anterolateral thigh may be used.

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with 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 international normalised ratio (INR) blood-clotting testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular

vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.

Multidose vials contain at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose.

Care should be taken to ensure a full dose is administered. Where a full dose cannot be extracted, the remaining volume should be discarded.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

2.3. Dosage

Individuals aged 12 years to 17 years

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine dose is 0.3ml.

Children aged 5 years to 11 years

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine dose is 0.3ml.

Children aged 6 months to 4 years

Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine dose is 0.3ml of the diluted vaccine.

2.4. Frequency

Individuals aged 12-17 years

A single dose of Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine dose regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, the dose should be given at least three months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose).

The only exception to the three months interval would be where individuals were about to receive or increase the intensity of an immunosuppressive treatment, and therefore a better response would be made if immunised prior to that treatment commencing. In this unusual scenario, the interval for all vaccine products may be reduced to a minimum of three weeks.

Individuals aged 5-11 years

A single dose of Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA vaccine regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, the dose should be given at least three months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose).

The only exception to the three months interval would be where individuals were about to receive or increase the intensity of an immunosuppressive treatment, and therefore a better response would be made if immunised prior to that treatment commencing. In this unusual scenario, the interval for all vaccine products may be reduced to a minimum of three weeks.

Individuals aged six months to 4 years

Primary immunisation

Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA vaccine course consists of two separate doses of 0.3ml each, a minimum of 12 weeks apart.

In those who have already received one previous dose of COVID-19 vaccination a single dose of Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA Vaccine dose, should be given at least three months (12 weeks) after any previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose) to complete the primary course.

Reinforcing dose

For those who have previously received primary vaccination a single dose of Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA vaccine. The dose should be given at least three months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose).

Individuals identified as meeting the definition for severe immunosuppression

Additional doses for those identified as meeting the definition for severe immunosuppression (as defined in **The Green Book COVID-19 Chapter)** may be required.

From 2023, for most individuals aged 5 years and above, the primary course of COVID-19 vaccine is an offer of a single dose of vaccine, provided only during seasonal campaigns. Individuals who become or have recently become severely immunosuppressed (i.e. those commencing immunosuppressive therapy or those who have developed an immunosuppressive condition) should be considered for additional doses (as outlined below).

Previously unvaccinated individuals who become or have recently become severely immunosuppressed should be considered for a first dose of vaccination, regardless of the time of year. Further doses should then be offered on the basis of specialist clinical judgement (see below).

Vaccinated individuals who become or have recently become severely immunosuppressed should be considered for an additional dose of COVID-19 vaccine, regardless of their past vaccination history and the time of year. The additional dose of vaccine should be offered at a minimum interval of three months from any previous doses, to extend protection until the next seasonal campaign.

Clinical judgement should be used to decide which individuals should be given an additional dose soon after their diagnosis rather than waiting for the next campaign and thus getting extra protection during the season, particularly over the winter, and at the same time as other high risk groups. The optimal timing should also take account of the degree of immune suppression (see **The Green Book COVID-19 Chapter** section on timing). Second doses should ideally be given between 8-12 weeks from the previous dose, to extend protection. This interval may be reduced to three weeks on specialist clinical advice to maximise short term protection, bearing in mind that response may be less durable. As above, subsequent doses may be optimally delivered during the next regular campaign.

In contrast to other eligible risk groups, those who are eligible for a vaccination due to severe immunosuppression but miss vaccination during the campaign period, may be considered for a booster at a later date based on individual clinical judgement, balancing their immediate level of risk against the advantages of waiting till the next seasonal campaign.

Additional doses are covered by this PGD.

Revaccination of individuals who have received a haemopoietic stem cell transplant or CAR-T treatment

In accordance with the schedule recommended by the Scottish Haematology Society **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.**

2.5. Duration of treatment

See frequency section.

2.6. Maximum or minimum treatment period

See frequency section.

2.7. Quantity to supply/administer

See frequency section.

2.8. ▼ black triangle medicines

Yes.

Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard**

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

The vaccine marketing authorisation holder's SmPC states that close observation for at least 15 minutes is recommended following vaccination. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant (in 2021), the UK Chief Medical Officers **recommended temporary suspension** of this requirement. This temporary suspension in individuals without a history of allergy was also agreed by the Commission on Human Medicines. The advice to suspend the routine 15 observation period has since been extended to all the currently available COVID-19 vaccines when used in the NHS programme.

Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule**.

The vaccine marketing authorisation holder's SmPC states that a primary course for those aged six months to four years of age consists of three doses. This is superseded by JCVI advice for a two dose primary schedule as set out in **The Green Book COVID-19 Chapter**.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.

Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to National Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.

2.11. Storage requirements

General requirements

During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright.

NHS Board guidance on Storage and Handling of vaccines should be observed.

In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal.

The manufacturer may advise of updated storage requirements and product stability: as new data becomes available, vaccine should be stored in accordance with updated recommendations from the manufacturer.

Vaccine specific requirements

Comirnaty LP.8.1 30 micrograms/dose dispersion for injection COVID-19 mRNA vaccine, pre-filled syringe

The vaccine should be stored refrigerated at +2°C to +8°C in the original package in order to protect from light.

Do not freeze.

Prior to use, pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C and 30 °C and can be handled in room light conditions.

Comirnaty LP.8.1 10 micrograms/dose dispersion for injection COVID-19 mRNA vaccine

Once thawed, the vaccine may be stored refrigerated at +2°C to +8°C protected from light for up to 10 weeks (within shelf life). Once thawed the vaccine should not be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C and thawed vials can be handled in room light conditions.

Comirnaty LP.8.1 3 micrograms/dose dispersion for injection COVID-19 mRNA vaccine

Once thawed, the vaccine may be stored refrigerated at +2°C to +8°C protected from light for up to 10 weeks (within shelf life) if not used (needle-punctured). Once thawed the vaccine should not be re-frozen.

The vaccine should be diluted as close to use as possible. However, reconstituted vaccine which is not required immediately must be used within 12 hours from the time of dilution and stored between +2°C to +30°C. Thawed vials can be handled in room light conditions.

The vaccine vial has space to write the date and time that the vial should be discarded following dilution (calculation: time of dilution + 12 hours); write this on the vial label.

2.12. Additional information

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.

There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.

Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient 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.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

The most frequently reported adverse reactions are injection site pain, swelling or redness, fatigue, headache, myalgia, chills, arthralgia, pyrexia, nausea, diarrhoea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination.

Uncommon side effects include feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak or lack of energy/sleepy, decreased appetite, excessive sweating and night sweats.

Lymphadenopathy: Swollen axilla or neck glands on the same side as the vaccination site can occur as a common reaction, which can last for up to 10 days.

Myocarditis and pericarditis: Very rare reports of myocarditis and pericarditis have been observed following vaccination with mRNA COVID-19 vaccines. These cases have primarily occurred within 14 days following vaccination, and more often in younger men. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Recipients should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

Heavy menstrual bleeding has been reported after COVID-19 vaccination. In most cases, this is self-limiting.

Uncommonly, benign and self-limiting cases of Erythema Multiforme have been reported associated after vaccination.

In the event of a severe adverse reaction individuals should be advised to seek medical advice.

For full details/information on possible adverse reaction, refer to manufacturer's product literature or SmPC.

3.2. Reporting procedure for adverse reactions

Healthcare professionals and individuals/carers should report all suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard.**

Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.

Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the MHRA Yellow Card Scheme. **The Green Book Vaccine safety and adverse events following immunisation chapter (8)** gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in **The Green Book Vaccine safety and adverse events following immunisation chapter (8)**, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'.

Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.

3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Immunisation promotional material may be provided as appropriate

Individual advice/follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently:
    - chest pain
    - shortness of breath
    - feelings of having a fast-beating, fluttering, or pounding heart
- As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://www.mhra.gov.uk/yellowcard**
- As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine.

- When administration is postponed advise the individual how future vaccination may be accessed.

3.4. Observation following vaccination

Following immunisation, individuals remain under observation in line with NHS Board policy.

Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre.

As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

An observation period when indicated after clinical assessment in individuals with a history of allergy as set out in Table 5 and flowchart in **The Green Book COVID-19 Chapter**.

Vaccinated individuals should be informed about 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.

3.5. Follow up

Not applicable.

3.6. Additional facilities

A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes.

The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Characteristics of staff authorised under the PGD

4.1. Professional qualifications

The following classes of registered healthcare practitioners are permitted to administer this vaccine:

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- 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.
- optometrists registered with the General Optical Council.

4.2. Specialist competencies or qualifications

Persons must only work under this PGD where they are competent to do so.

All practitioners operating this PGD:

- demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine.

- have met the requirements of the NES Proficiency document -COVID-19 vaccine administration for registered staff or the NES Proficiency document – COVID-19 vaccine administration. This NES Proficiency document can be found at TURAS Learn at: **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines**

All persons operating this PGD:

- must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it.
- must be familiar with the vaccine product and alert to changes in the manufacturer's product information/summary of product characteristics information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under the PGD.

Employer

- The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.
- As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

5. Audit trail

Record the following information:

- valid informed consent was given
- name of individual, address, date of birth and GP with whom the individual is registered if possible
- name of person that undertook assessment of individual's clinical suitability and subsequently administered the vaccine
- name and brand of vaccine
- date of administration
- dose, form and route of administration of vaccine
- batch number
- where possible expiry date
- anatomical site of vaccination
- advice given, including advice given if excluded or declines immunisation
- details of any adverse drug reactions and actions taken
- administered under PGD

Records should be kept in line with local procedures.

Local policy should be followed to encourage information sharing with the individual's General Practice.

All records should be clear, legible and contemporaneous and in an easily retrievable format.

6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book]**.
- **Immunisation against Infectious Disease [Green Book] COVID-19**
- **Comirnaty LP.8.1 30 micrograms/dose COVID-19 mRNA vaccine Summary of Product Characteristics**
- **Comirnaty LP.8.1 10 micrograms/dose COVID-19 mRNA vaccine Summary of Product Characteristics**
- **Comirnaty LP.8.1 3 micrograms/dose COVID-19 mRNA vaccine Summary of Product Characteristics**
- **Educational resources for registered professionals produced by National Education for Scotland**
- All relevant **JCVI statements**
- All relevant Scottish Government advice including the **relevant CMO letter(s)**
- **Scottish Haematology Society Advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**
- **Professional Guidance on the Administration of Medicines in Healthcare Settings 2019**
- **Professional Guidance on the Safe and Secure Handling of Medicines**
- **Scottish Government Section 47 certificate of incapacity**
- **NES adults with incapacity**

7. PGD for administration of COVID-19 mRNA vaccines to individuals aged under 18 years version 7.0 (valid from 1 April 2026 and expires 31 August 2026): authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it. I agree to administer COVID-19 vaccines to individuals aged under 18 years only in accordance with this PGD.

Name of professional	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 **NHS Greater Glasgow and Clyde** for the above-named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name …….

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

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

8. Version history

Version	Date	Summary of changes
1.0	1 September 2023	Version 1.0 New PGD
2.0	14 September 2023	• Updated throughout to include XBB.1.5 variant vaccines. • Cautions section updated to remove deferral for two weeks after COVID-19 infection. • Frequency section updated to align with Green Book chapter advice on additional doses for those identified as meeting the definition for severe immunosuppression. • Use outwith SmPC – updated following change in SmPC for Comirnaty BA4.5 and minor changes to wording on post vaccination observation. • Observation following vaccination section - minor changes.
2.1	18 September 2023	• Section 2.1 updated to highlight that Comirnaty Omicron XBB.1.5 (3micrograms/dose) is a concentrate for dispersion for injection which requires dilution before use. • Section 2.3 (dosage) updated to highlight at dose of Comirnaty Omicron XBB.1.5 (3micrograms/dose) is 0.2ml of diluted vaccine. • Section 2.11 (storage) updated to include recommendations on storage of vaccine after dilution.
2.2	3 October 2023	• Section 2.4 Frequency section updated for Individuals aged six months to 4 years
3.0	1 March 2024	The following changes to version 2.2 of the PGD have been made: • PGD updated to reference mRNA vaccines only. • PGD updated to remove reference to bivalent Original/Omicron BA. 4-5 vaccines. • Inclusion criteria amended to include individuals invited, or eligible in accordance with the

Version	Date	Summary of changes
		recommendations in Green Book **Chapter 14a**, and/or in line with subsequent correspondence/publications from Scottish Government. • Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment. • Frequency section updated to reflect updated Green Book Chapter advice for Spring 2024 programme and for severely immunosuppressed individuals. • Is the use outwith the SmPC and observation following vaccination sections updated to remove advice from Scottish Government on 5 minute wait.
3.1	13 March 2024	Minor typographical changes to recent changes section to correct previous version numbers
4.0	16 September 2024	The following changes to version 3.1 of the PGD have been made: • Updated throughout to include JN.1 vaccines • Co-administration with other vaccines updated to include RSV vaccine. • Warnings section updated to include statement that Erythema Multiforme has been reported associated after vaccination.
5.0	19 March 2025	The following changes to version 4.0 of the PGD have been made: • Section 1.4 Co administration with other vaccines section updated to include Pregnant women can safely have Abrysvo® co-administered with influenza vaccine, anti-D immunoglobulin or COVID-19 vaccine. • Section 2.10 information added to clarify revaccination of patients following haematopoietic

Version	Date	Summary of changes
		stem cell transplant of CAR-T treatment is considered off-label but is in accordance with the **Scottish Haematology Society schedule**.
6.0	1 September 2025	The following changes to version 5.0 of the PGD have been made: • Green Book COVID-19 Chapter reference updated throughout • Updated throughout to remove reference to Comirnaty JN.1 30 micrograms/dose and replace with Comirnaty KP.2 30 micrograms/dose • Updated throughout to remove reference to Comirnaty JN.1 10 micrograms/dose and replace with Comirnaty LP.8.1 10 micrograms/dose • Updated throughout to remove reference to Comirnaty JN.1 3 micrograms/dose and replaced with Comirnaty LP.8.1 3 micrograms/dose • Section 1.2, Inclusion criteria updated to remove vaccination in relation to international travel • Section 1.4 Vaccination of individuals vaccinated overseas or as part of clinical trials updated • Section 2.1 Name of medicine, updated in relation to content of vaccine
7.0	24 March 2026	The following changes to version 6.0 of the PGD have been made: • Minor rewording, layout and formatting changes for clarity and consistency with other PHS PGDs. • Updated throughout with vaccines recommended for use in the Spring 2026 programme. • Action if excluded updated to include reference to Nuvaxovid PGD where mRNA products are considered not clinically suitable for individuals over the age of 12 years. • Advice to patient or carer section updated. • References updated throughout.