Public Health Scotland

Administration of Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioTech)

Patient group direction (PGD) template

Publication date: 13 March 2023

Version 1.4

Translations and other formats are available on request at:

phs.otherformats@phs.scot

0131 314 5300

Public Health Scotland is Scotland's national agency for improving and protecting the health and wellbeing of Scotland's people.

www.publichealthscotland.scot

Most recent changes

Version	Date	Summary of changes
1.4	13 March 2023	The following sections have been updated: • Cautions section updated – updated wording on co-administration with other vaccines to align with updated Green Book chapter. • Cautions section updated – updated wording on past history of COVID-19 infection to align with updated Green Book chapter. • Action if excluded section updated to remove recent COVID test. • Frequency section updated – section on severe immunosuppression updated to align with updated Green Book chapter. • Frequency section updated – section on reinforcing vaccine (interval) updated to align with updated Green Book chapter. • Use out with SmPC section updated to align with Green Book chapter advice on observation after vaccination. • Use out with SmPC section updated as SmPC now includes booster vaccination • Warning section – minor amendments to align with updated Green Book chapter. • Observation following vaccination section updated to align with Green Book chapter advice on observation after vaccination.

Contents

Authorisation

PGD Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech)

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 qualified health professionals who may administer Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) under this PGD can only do so 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 will 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 has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS …… by:

Doctor (Name / Signature)…….....
Pharmacist (Name /Signature) ……...
Nurse (Name / Signature) ……

Approved on behalf of NHS…… by:

Medical Director (Name / Signature) ……..
Director of Pharmacy/Senior Pharmacist (Name / Signature) …….
Clinical Governance Lead (Name / Signature) ……
Date approved: ……

Effective from: 13 March 2023 Review date: 31 March 2024

1. Clinical situation

1.1. Indication

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Green Book **Chapter 14a** and subsequent correspondence/publications from Scottish Government.

1.2. Inclusion criteria

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech should be offered to individuals aged 5-11 years in accordance with the recommendations in Green Book **Chapter 14a**.

National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.

Valid consent has been given to receive the vaccine.

1.3. Exclusion criteria

Individuals who:

- have had a previous systemic anaphylactic reaction to any COVID-19 vaccine.
- have had a prior systemic allergic reaction to any component (excipient) of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) e.g. 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.

- are under 5 years of age or aged over 12 years.

- 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 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 a precautionary advice to avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period.

- have developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination.

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 vaccine. 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 Green Book **Chapter 14a, table 5.**

Where individuals have experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the flowchart in Green Book **Chapter 14a** in relation to administration of subsequent doses.

Green Book **Chapter 14a** 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

As all of the early COVID-19 vaccines 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 most 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 polysaccharide vaccine, pertussis-containing vaccines and LAIV, HPV, MenACWY and Td-IPV vaccines in school age children).

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.

Clinical trial participants

Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes).

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.

As clinical deterioration can occur up to two weeks after infection vaccination should ideally be deferred until clinical recovery.

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 should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated.

Inform or refer to the clinician in charge.

In case of postponement due to acute 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.

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

1.6. Action if patient declines

Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.

Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine.

Inform or refer to the clinician in charge.

Document advice given and decision reached.

2. Description of treatment

2.1. Name of medicine/form/strength

Comirnaty® 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified).

10micrograms/0.2ml dose concentrate for dispersion for injection multidose vials.

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is a multidose vial and must be diluted with 1.3ml of 0.9% sodium chloride before use. 1 vial contains 10 doses of 10 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).

2.2. Route of administration

After dilution, vials of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) contain 10 doses of 0.2 ml of vaccine. In order to extract 10 doses from a single vial, low dead-volume syringes and/or needles should be used. If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.

Each dose must contain 0.2 ml of vaccine.

If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 ml, discard the vial and any excess volume.

Any unused vaccine should be discarded 12 hours after dilution.

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 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.

Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer’s product literature or SmPC.

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 INR 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.

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

2.3. Dosage

The dose of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is 10 micrograms contained in 0.2ml of the diluted vaccine.

2.4. Frequency

Primary immunisation

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) course consists of two separate doses of 0.2ml each, a minimum of 21 days apart.

For Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech), there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used.

Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used.

Operationally, using the same minimum interval for all products will simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection.

If an interval longer than the recommended interval is left between doses in the two-dose primary schedule, the second dose should still be given. The course does not need to be restarted.

The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined above may be followed to enable the vaccine to be given whilst their immune system is better able to respond.

Individuals who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the two-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression.

5 -11 year olds in risk group

Children aged 5 – 11 years in a clinical risk group (as defined in Green Book **Chapter 14a**), or who are about to commence immunosuppression or who are a household contact of someone who is immunosuppressed (as defined in the Green Book), should be offered two 10 micrograms doses of Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) with an interval of 8 weeks between the first and second doses.

5 -11 year olds not in risk group

Children aged 5 – 11 years not in a risk group (as defined in Green Book **Chapter 14a** should be offered two 10 micrograms doses of Comirnaty® (COVID-19 mRNA

vaccine, Pfizer/BioNTech) with an interval of 12 weeks between the first and second doses.

Children aged 5-11 years who have commenced immunisation with the 10 microgram paediatric dose of Pfizer BioNTech and then turn 12 years of age should also complete vaccination with the paediatric dose. An adult/ adolescent dose is an acceptable alternative if this is the only supply available.

Severe immunosuppression

For those identified as meeting the definition for severe immunosuppression (as defined in Green Book **Chapter 14a)** in proximity of their first or second vaccine doses in the primary schedule, in line with specialist advice, a third primary dose should be offered. The third primary dose should be given at least 8 weeks after the second dose.

In general, vaccines administered during periods of minimum immunosuppression are more likely to generate better immune responses. Therefore, any additional doses should ideally be given with special attention paid to current or planned immunosuppressive therapies. For example:

● where possible, third primary or additional booster doses should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent

● alternatively, consideration should be given to vaccination during a treatment ‘holiday’ or when the degree of immunosuppression is at a minimum

Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after immunosuppressive therapy should only be taken after due consideration of the risks of exacerbating their underlying condition, as well as the risks from COVID-19.

Pfizer BioNTech (Comirnaty® 10 micrograms/dose) is recommended for 5-11 year olds for the third primary dose for those with severe immunosuppression.

Reinforcing vaccination

Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) as a booster in those are immunosuppressed as defined in table 3 and 4 of Green Book Chapter 14a and who have received primary immunisation (and previous boosters) should be offered a single dose.

Boosters should be offered around six months from the previous dose, but can be given three months (12 weeks) from the previous dose.

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.

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is subject to additional monitoring and has been designated ▼

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://yellowcard.mhra.gov.uk.**

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use out with the SmPC?

The vaccine marketing authorisation holder's SmPC states that the vaccine should be given as a series of two doses (0.2ml, each) 21 days apart.

This is superseded by the JCVI recommendation of a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used.

The vaccine marketing authorisation holder's summary of product characteristics states that a booster may be given six months after a previous dose. This is superseded by the JCVI that the minimum interval for a booster is three months after a previous dose.

The vaccine marketing authorisation holder's summary of product characteristics 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, 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 minute observation period applies to all the currently available COVID-19 vaccines, including the bivalent mRNA products and both the Novavax and Sanofi vaccines.

The Scottish Government has made further recommendations that all doses of COVID-19 vaccines be followed by a 5 minute observation period.

The vaccine marketing authorisation holder's summary of product characteristics states that the vaccine is indicated in children aged 5-11 years. The use in children aged 5-11 years who commence immunisation with the 10 microgram paediatric dose of Pfizer BioNTech and then turn 12 years of age or those 12 year olds vaccinated in same academic/school year group as 11 year olds should complete

vaccination with the 10 microgram paediatric dose is outwith the SmPC but is aligned with advice from JCVI.

Vaccine should be stored according to the conditions detailed below. However, in the event of a deviation of these conditions where vaccine is assessed as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice.

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

Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 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.

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.

During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

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 become available; the vaccine may be stored in accordance with updated recommendations from the manufacturer.

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 may 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. Inclusion of antibody positive individuals in the Pfizer phase 3 analysis did not give any safety signals.

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 overall safety profile of Comirnaty in participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older.

The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%).

During post-marketing surveillance a number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae. The MHRA has advised the benefits of vaccination still outweigh any risk in most individuals. Individuals who have had myocarditis or pericarditis should be investigated, and a second or booster dose can be given once they are fully recovered in line with advice in Green Book **Chapter 14a**, under a PSD.

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.

In the event of a severe adverse reaction individual 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 Coronavirus Yellow Card Scheme. The Green Book, **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 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 individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Provide copy of Public Health Scotland post-vaccination leaflet.
- Clear information on the potential risks and benefits of vaccination should be provided to the parent/carer of the eligible child or young person prior to vaccination. Information provided should be accessible for young people should they wish to consent for vaccination.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required.
- Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection.
- Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms.
- 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://yellowcard.mhra.gov.uk**

- Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.

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

- When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.

3.4. Observation following vaccination

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.

According to the SmPC, it is recommended that all recipients of the Pfizer BioNTech, Moderna, Novavax and Sanofi vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers recommended suspension of this requirement for the two mRNA vaccines (Comirnaty and Spikevax) in both adults and children. 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 minute observation period applies to all the currently available COVID-19 vaccines, including the bivalent mRNA products and both the Novavax and Sanofi vaccines.

The Scottish Government has made further recommendations that all doses of COVID-19 vaccines be followed by a 5 minute observation period.

A longer observation period when indicated after clinical assessment in individuals with a history of allergy as set out in Green Book, **Chapter 14a**, Table 5 and flowchart.

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)
- 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 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

- **Immunisation against Infectious Disease [Green Book]**
- **Immunisation against Infectious Disease [Green Book] COVID-19**
- **Manufacturer's product information/ Summary of Product Characteristics**
- **Educational resources for registered professionals produced by National Education for Scotland**
- All relevant JCVI statements related to COVID-19 vaccination.
- All relevant Scottish Government advice including the relevant CMO letter(s)

7. PGD for administration of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) V1.4 (valid from 13 March 2023 and expires 31 March 2024): 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 Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 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 **[insert name of organisation]** 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	17 January 2022	Version 1.0 new national specimen patient group direction produced.
1.1	25 February 2022	The following sections have been updated: • Caution section updated to include updated figure on managing patients with a history of allergy from Green Book chapter. • Caution section updated with minor changes to align with Green Book chapter advice on vaccination of clinical trial participants. • Caution section updated with to align with Green Book chapter advice on vaccination of individuals with a past history of COVID-19 infection. • Frequency section updated with recommendations for vaccination of those aged 5-11 years not in a clinical risk group and to align with wording in Green Book chapter on vaccination of those turn aged 12 years after first dose. • Is the use out with the SmPC section updated to align with wording in Green Book chapter. • Appendix 1 updated to align with amendments to figure 1 on managing patients with a history of allergy. • Reference section has been updated.
1.3	22 August 2022	This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. The following sections have been updated: • Cautions section updated to present more concise advice for individuals with a history of allergy. • Cautions section updated to present advice for individuals with thrombocytopenia • Cautions section updated to present advice for individuals with Guillain-Barré syndrome

Version	Date	Summary of changes
		• Frequency section updated to align with advice for autumn 2022 vaccination programme. • Outwith SmPC section updated to highlight that booster dose is off label but in accordance with JCVI advice.
1.4	13 March 2023	The following sections have been updated: • Cautions section updated – updated wording on co-administration with other vaccines to align with updated Green Book chapter. • Cautions section updated – updated wording on past history of COVID-19 infection to align with updated Green Book chapter. • Action if excluded section updated to remove recent COVID test. • Frequency section updated – section on severe immunosuppression updated to align with updated Green Book chapter. • Frequency section updated – section on reinforcing vaccine (interval) updated to align with updated Green Book chapter. • Use out with SmPC section updated to align with Green Book chapter advice on observation after vaccination. • Use out with SmPC section updated as SmPC now includes booster vaccination • Warning section – minor amendments to align with updated Green Book chapter. • Observation following vaccination section updated to align with Green Book chapter advice on observation after vaccination.