NHS Greater Glasgow and Clyde

Patient Group Direction (PGD)

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

Note other COVID19 vaccines are not covered by this PGD – separate PGDs will be available.

Publication date: 25 March 2022

PGD No: 2022/2366

Version 1.2
Effective from: 25 March 2022
Review date: 31 December 2022

Most Recent Changes

Version	Date	Summary of changes
1.2	25/03/22	The following sections have been updated: Cautions section updated to clarify advice on vaccination of individuals with a past history of COVID-19 infection. Advice to patient or carer section updated with advice on fever following vaccination.

Contents

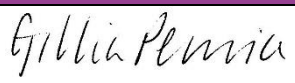
Authorisation

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

This Patient Group Direction (PGD) 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.

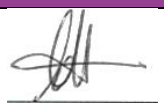
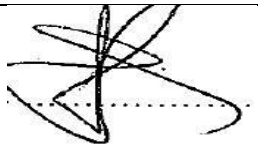
The qualified health professionals who may administer Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/summary of product characteristics (SPC) 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.

Doctor	Dr Gillian Penrice, Consultant in Public Health	
Pharmacist	Val Reilly, Public Health Protection Pharmacist	
Nurse	Hilda Crookshanks (Health Protection Nurse Specialist)	

Date 25/03/2022

Approved on behalf of NHS Greater Glasgow and Clyde by ADTC Patient Group Direction Sub Committee representatives:

Chair	Dr Craig Harrow	
Senior Pharmacist	Elaine Paton, Senior Prescribing Adviser	
Nurse Director Representative	John Carson, Lead Nurse North Sector	

Effective from: 25/03/2022 **Review date:** 31/12/2022

Clinical situation

Category	Description
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 Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book'; statements from Joint Committee on Vaccination and Immunisation (JCVI); and subsequent correspondence/publications from Scottish Government.
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 Chapter 14a of the Green Book and JCVI advice. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the frequency section).
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic anaphylaxis reaction to any COVID-19 vaccine. • Those who have had a prior systemic allergic reaction to any component (excipient) of Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) e.g. polyethylene glycol

Category	Description
	• Those with 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. • Those with 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. • Those with a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • Those in whom no valid consent has been received • Those who are under 5 years of age or aged over 12 years • Those with 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. • Those with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those 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. • Those who developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination
Cautions/ **need for further advice/ circumstances when further advice should be sought from a doctor**	The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID 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 The Comirnaty® 10 microgram/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of mRNA vaccines.

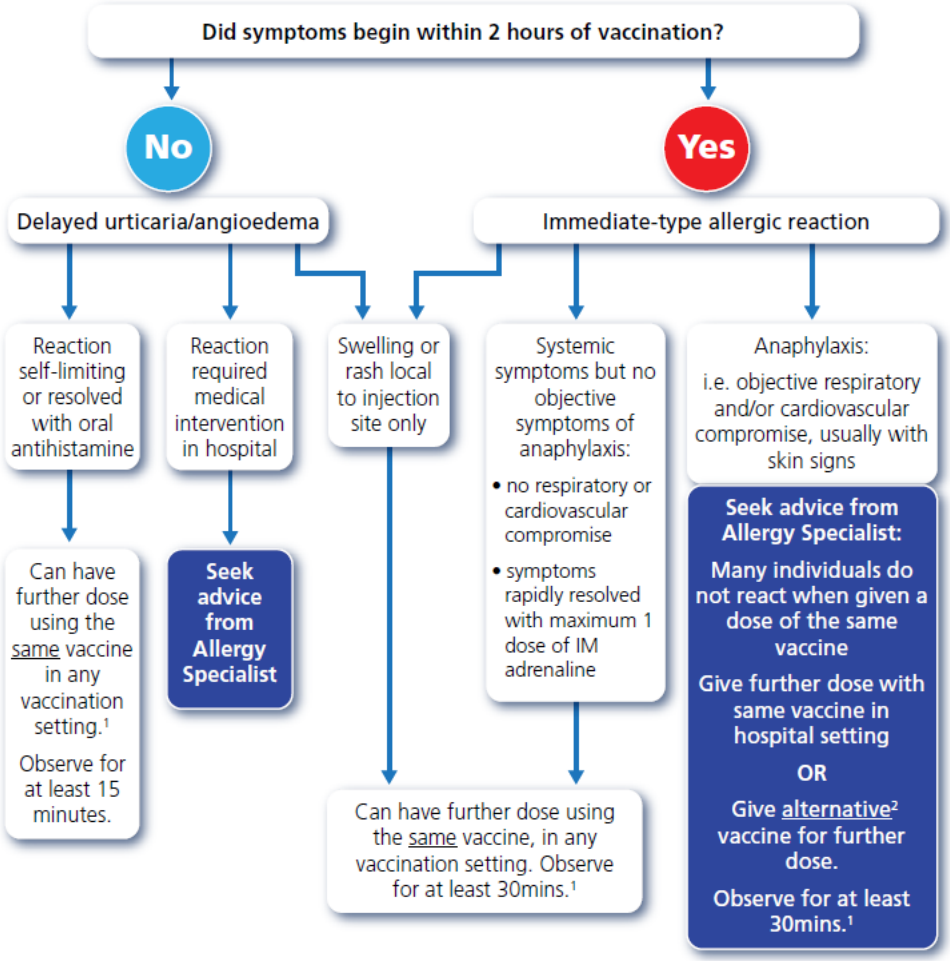
Category	Description
	Published data now show that some individuals with prior allergic reaction to PEG containing medicines (eg. PEG-asparaginase) can tolerate the PfizerBioNTech vaccine (although the historical reaction may have been due a non-PEG component). Expert advice should be obtained and if a decision is made to administer an mRNA vaccine, then this should only be done in hospital under medical supervision under a patient specific direction. There is now evidence that many individuals with initial apparent allergic reaction to an mRNA vaccine can tolerate a second dose of the same vaccine. Where there were no objective signs of anaphylaxis and symptoms rapidly resolved (with no more than 1 dose of IM adrenaline), a further dose of the same vaccine can be given in any vaccination setting. Observe for 30 minutes. If the reaction might have been anaphylaxis, obtain expert advice; if a decision is made to administer the same vaccine, then this should be done under medical supervision in the hospital setting under a patient specific direction. The COVID-19 chapter of the Green Book 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. Observe for 15 minutes. Figure 1 summarises the management of patients with a history of allergy. No specific management is required for individuals with a family history of allergies **Appendix 1** provides an accessible version of Figure 1. **Figure 1: Management of patients with a history of allergy**

Category	Description

	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 AstraZeneca vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Figure 2 shows the Green Book Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.

Figure 2: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine

Category	Description
	 [1] Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination [2] If reaction was to AstraZeneca vaccination, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give the same or alternative mRNA vaccine in hospital setting. Those with an anaphylaxis immediate-type allergic reaction are excluded from receiving vaccination under this PGD – a patient specific direction is required if further doses are offered. 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

Category	Description
	later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. 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 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. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children* should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen to avoid confusing the differential diagnosis. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. The four-week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high

Category	Description
	incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits. In younger people, after natural infection or a single dose of vaccine, protection from serious complications of COVID-19 infection is likely to be high for a period of months. Limited evidence suggests that countries with longer intervals between primary doses (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Based on extrapolation from this limited evidence, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Therefore, vaccination should ideally be deferred until twelve weeks from onset (or sample date) in children and young people under 18 years who are not in high risk groups (see * below). This interval may be reduced to eight weeks in healthy under 18 year olds when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Current advice in PIMS-TS cases also suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at high risk of infection and/or who are fully recovered. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection. *high risk will include children and young people under 18 years as defined in tables 3 and 4 of COVID-19 chapter of Green Book and includes clinical risk groups and individuals who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals who are immunosuppressed.
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. 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 or recent positive COVID test 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.
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.

Category	Description
	Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine. Document patient's declined consent and advice given.

Description of treatment

Category	Description
Name of medicine	Comirnaty® 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech)
Form/strength	Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 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).
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 summary of product characteristics. 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

Category	Description
	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.
Dosage	The dose of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is 10 micrograms contained in 0.2 mL of the diluted vaccine
Frequency	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 2-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.

Category	Description
	5-11 year olds in risk group Children aged 5 - 11 years in a clinical risk group (as defined in the COVID-19 chapter of Green Book), 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 the COVID-19 chapter of Green Book), 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. JCVI have advised that children aged 12 years may be vaccinated with the 10 microgram paediatric dose of Pfizer BioNTech alongside those aged 11 years in the same academic year. 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 in proximity of their first or second vaccine doses in the primary schedule, in line with specialist advice, for a third primary dose (as defined in COVID-19 chapter of Green Book) in accordance with recommendations in the JCVI advice on third dose primary vaccine. The third primary dose should be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: a) where possible the third primary dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent, b) if not possible, consideration should be given to vaccination during a treatment ‘holiday’ or at a nadir of immunosuppression between doses of treatment. For those aged over 18 years, JCVI advises a preference for mRNA vaccines - Pfizer BioNTech (Comirnaty®) or Moderna (Spikevax®) - for the third primary dose for those with severe immunosuppression. Pfizer BioNTech (Comirnaty® 10 micrograms/dose) is preferred for 5-11 year olds.
Duration of treatment	See Dose and frequency of administration above.

Category	Description
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 10 micrograms in 0.2mL per administration.
▼ black triangle medicines	Yes, Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) has been designated ▼ All adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme **https://coronavirus-yellowcard.mhra.gov.uk/**
Legal category	Prescription only medicine (POM).
Is the use out with the SPC?	The vaccine marketing authorisation holder's summary of product characteristics 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 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 have recommended temporary suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines 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 to 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 SPC 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.

Category	Description
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 becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.
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. 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.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and	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.

Category	Description
management of these	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%). Recently a number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine from Israel and the USA. 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 the COVID-19 chapter of the Green Book, 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 summary of product characteristics.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: **https://coronavirus-yellowcard.mhra.gov.uk/** As this vaccine is labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme **https://coronavirus-yellowcard.mhra.gov.uk/** 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. Chapter 8 of the Green Book 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

Category	Description
	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.
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. • 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. They may be advised to take a COVID-19 test. • 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: o chest pain o shortness of breath o 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

Category	Description
	• 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.
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 Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech and Moderna 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 have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. There is no routine requirement for observation following COVID-19 Vaccine AstraZeneca. The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period should be observed when indicated after clinical assessment as set out in Figure 1 and Figure 2 (above). 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.
Follow up	Not applicable
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

Category	Description
	anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) • 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
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All practitioners operating this PGD must: • 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 manufacturers 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

Category	Description
	• 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.
Continuing education and training	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 this PGD.

Audit trail

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that 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 kept in line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] COVID-19 **https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a** Manufacturer's product information/ Summary of Product Characteristics **https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19** Educational resources for registered professionals produced by National Education for Scotland **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All relevant JCVI statements related to COVID-19 vaccination. All relevant Scottish Government advice including the relevant CMO letter(s)

PGD for administration of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) v1.2 Valid from: 25/03/2022 Expiry: 31/12/2022 - 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.

Appendix 1 – 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 the COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine, (for known PEG allergy see Green Book chapter 14a COVID-19)
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 pre-treatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a patient 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 the reaction was to AstraZeneca vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Version History

Version	Date	Summary of changes
1.0	17/01/22	Version 1.0 new national specimen patient group direction produced.
1.1	25/02/22	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 SPC 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.
1.2	25/03/22	The following sections have been updated: Cautions section updated to clarify advice on vaccination of individuals with a past history of COVID-19 infection. Advice to patient or carer section updated with advice on fever following vaccination.