Patient Group Direction
for Registered Healthcare Practitioners legally permitted to operate under a PGD to administer

Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine Pfizer/BioNTech)

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1. Clinical condition to which the patient group direction applies

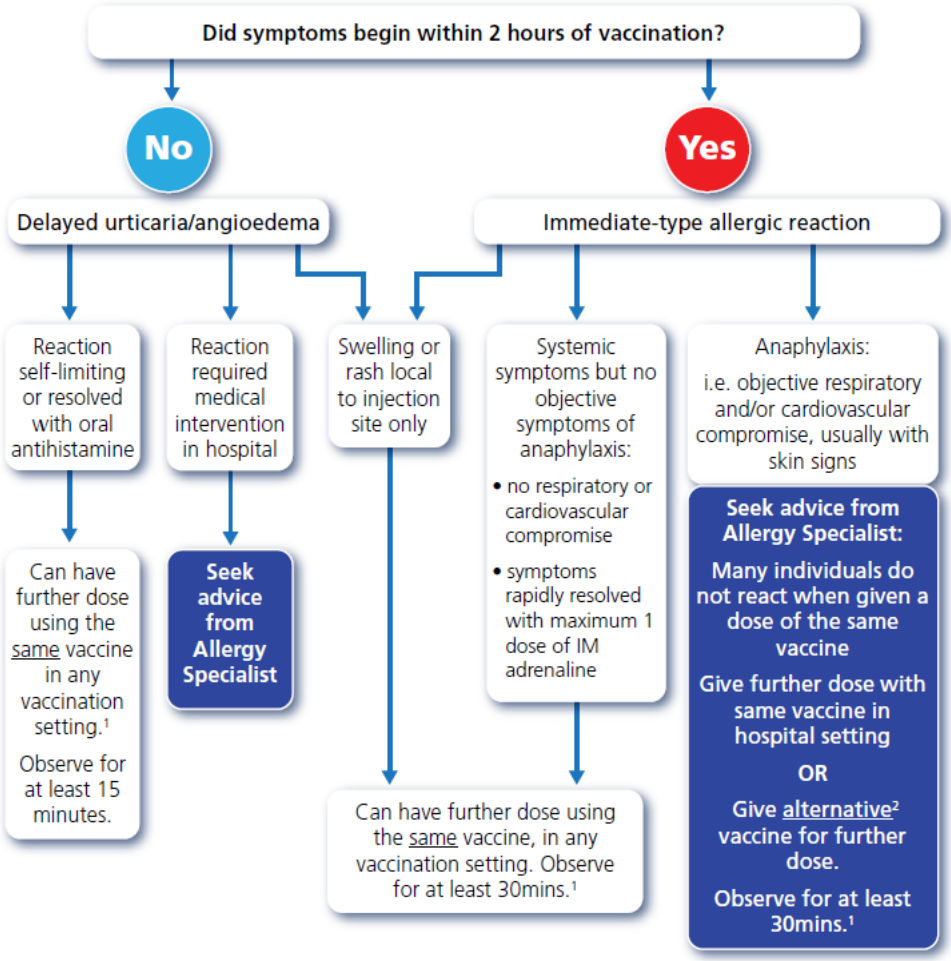
Indication	Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation 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® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) should be offered to all individuals aged 12 years and over 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). • Valid consent to treatment according to NHS Fife policy
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® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) e.g. polyethylene glycol. • 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 to treatment has been received according to NHS Fife policy • Those who are under 12 years of age • 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 / Circumstances when further advice should be sought from a senior clinician	• It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered / supplied • 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 health protection team. Individuals with a history of allergy • The Comirnaty® 30 micrograms/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. • Published data now show that some individuals with prior allergic reaction to PEG containing medicines (e.g. PEG-asparaginase) can tolerate the PfizerBioNTech vaccine (although the historical reaction may have been due to 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. Observation for 15 minutes is recommended. 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**

	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 reactio to COVID-19 vaccine • prior systemic allergic reaction to a componen 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 othe appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was t AstraZeneca vaccine give alternative vaccine in an 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



[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 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 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).

- An exception to this is shingles vaccination, where a seven day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine.
- 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.

Pregnancy and breastfeeding

- JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the pregnant individual or the unborn child
- Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data does not indicate any harm to pregnancy. JCVI has therefore advised that, individuals who are pregnant should be considered as falling into a clinical risk group (JCVI Priority Cohort 6 for COVID-19 vaccination). There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far. These vaccines are therefore the preferred vaccines to offer to pregnant individuals (for those under 18 years Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is preferred). Clinicians (such as obstetricians, midwives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination should discuss the risks and benefits of vaccination with the individual, who should be told about the absence of safety data for the vaccine in pregnancy.
- There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding individuals may be offered 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 individual's clinical need for immunisation against COVID-19.

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 (see * below) 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 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	• Do not use the PGD • 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 treatment	• 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 • Document patient's declined consent and advice given

2. Medication details

Name strength & formulation of drug	• Comirnaty® 30 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) • Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) • Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine Pfizer/BioNTech) 30micrograms/0.3ml dose concentrate for dispersion for injection multidose vials • Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine Pfizer/BioNTech) is a multidose vial and must be diluted with 1.8mL of 0.9% sodium chloride before use. 1 vial contains 6 doses of 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles). Sodium Chloride solution available separately and is not contained within the same box as the vaccine • After dilution, vials of Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine Pfizer/BioNTech) contain 6 doses of 0.3 mL of vaccine. In order to extract 6 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 a sixth dose from a single vial. • Irrespective of the type of syringe and needle: ▪ Each dose must contain 0.3 mL of vaccine. ▪ If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume. ▪ Do not pool excess vaccine from multiple vials ▪ Any unused vaccine should be discarded 6 hours after dilution.
Route of administration	• Comirnaty® 30 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 clinician 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
Dosage	• The dose of Comirnaty® 30 micrograms/dose COVID-19 mRNA Vaccine is 30 micrograms contained in 0.3mL of the diluted vaccine
Frequency of administration	• Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine Pfizer/BioNTech) course consists of two separate doses of 0.3ml each, a minimum of 21 days apart • For both AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) and mRNA vaccines, 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 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 (preferably using the same vaccine as was given for the first dose if possible). 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. • Evidence suggests that those who receive mixed schedules, including mRNA and AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) make a good immune response, although rates of side effects with a heterologous second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. **12-15 year olds**

	Children and young people aged 12 to 15 years who are in recognised risk groups (as defined in COVID-19 chapter of Green Book) or who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed (as defined in COVID-19 chapter of Green Book) should receive two 30µg doses of Pfizer BioNTech vaccine at an interval of at least eight weeks. For children and young people aged 12 to 15 years who are not in a risk group or share living accommodation on most days with individuals of any age who are immunosuppressed, JCVI have now recommended that a second dose of vaccine should be offered after an interval of 12 weeks. This interval reflects the strong evidence of high levels of protection against severe disease from the first dose, although could be shortened to eight weeks when rapid protection is required, for example in periods of high incidence or circulation of a new variant In a vulnerable population. **16-17 year olds** Young people aged 16 to 17 years who are in a recognised clinical risk group (as defined in COVID-19 chapter of Green Book) and those who work in health and social care should receive two doses of vaccine at an interval of at least eight weeks. This includes those aged 16 to 17 years who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed (as defined in COVID-19 chapter of Green Book). Initially JCVI advised that young people aged 16-17 years who are not in a risk group should receive their first dose of vaccine. A second dose of vaccine is now offered at an interval of 12 weeks. This longer interval in this age group reflects the strong evidence of high levels of protection against severe disease from the first dose, although could be shortened to eight weeks when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. Emerging evidence also suggests that countries with longer schedules (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Although this latter evidence is limited, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Young people should be fully informed about the benefits and risks of the second dose and able to discuss the optimal timing for them. **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). 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®) is

preferred for 12-17 year olds. AstraZeneca COVID-19 vaccine (Vaxzevria®) is an option for individuals who have received this vaccine previously where mRNA vaccines are clinically contraindicated. In exceptional circumstances, persons aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered a third dose of AstraZeneca Vaxzevria vaccine following a decision by a health professional on a case-by-case basis.

Booster vaccination

Booster vaccination should not be given within three months (12 weeks) of completion of the primary course.

The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for boosting irrespective of the vaccine used for the primary course. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer BioNTech preferred for those aged 16-17 years and those aged 12-15 years in clinical risk groups. Both vaccines have been shown to give good immune responses in those already primed. The half dose of Moderna and is expected to have a lower rate of side effects (including myocarditis) than a full dose.

- Where mRNA vaccines are clinically contra-indicated, vaccination with AstraZeneca vaccine may be considered in those who had received at least one dose of this vaccine previously.
- Severely immunosuppressed individuals (aged 16 years and over) who have completed their primary course (three doses) should be offered a booster dose with a minimum of three months (12 weeks) between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now (provided there has been an interval of at least 8 weeks since the second primary dose) to avoid further delay. A fourth dose can be given in three months (12 weeks), in line with the clinical advice on optimal timing.
- All those aged 16 and 17 years should be offered a booster dose of 30 micrograms Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) no sooner than 3 months (12 weeks) after completion of their primary course.
- Children and young people aged 12 to 15 who are in a clinical risk group or who are a household contact of someone who is immunosuppressed should be offered a booster dose of 30 micrograms Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) no sooner than 3 months (12 weeks) after completion of their primary course.

Spring booster 2022

- JCVI have advised a further booster dose should be given around six months after the last dose to adults aged 75 years and over**; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed (as defined in COVID-19 chapter of Green Book).

**or who will turn 75 years by 30 June 2022

- The vast majority of people aged over 75 will reach an interval of around six months from their previous dose between March and June 2022. Although vaccination should ideally be offered around six months from any previous dose, operational flexibility may be used. For example, individuals in care homes or housebound patients may be offered the booster alongside other residents providing there is at least three months (12 weeks) from the previous dose.
- Immunosuppressed individuals who have received an additional primary dose

	may have received the booster (fourth) dose more recently. These latter individuals and other eligible people who received their last vaccine more recently should also be offered the booster during the spring campaign providing there is at least three months (12 weeks) from the previous dose. This will ensure they have additional protection against a potential summer wave and will align with their peers to facilitate an autumn programme. • Someone in an eligible group, who has received a full course of primary vaccination (two or three doses) but has not received their first booster by March 2022, may be given the spring booster in the campaign provided there is at least three months from the previous dose. An additional dose is not then recommended before the autumn. The vaccines offered should follow the age-appropriate advice as for other reinforcing doses (see below). The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for the additional booster irrespective of the vaccine used previously. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer BioNTech preferred for those aged 12-17 years in clinical risk groups.
Duration of treatment	• See Dose and frequency of administration above
Quantity to be supplied	• Administer 30 micrograms in 0.3mL per administration
Patient advice verbal and written	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 • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to people of child bearing years • 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: ➢ 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: https://coronavirus-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
Legal category	• Prescription only medicine (POM)
Use outwith SPC	• The vaccine marketing authorisation holder's summary of product characteristics states that the vaccine should be given as a series of two doses (0.3mL, 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 dose (third dose) of Comirnaty may be administered intramuscularly at least 6 months after the second dose in individuals 18 years of age and older. This is superseded by the JCVI advice as set out in the COVID-19 chapter of Green Book for the third primary dose vaccination in those with severe immunosuppression in proximity of their first or second doses in the primary schedule, by the JCVI advice on the UK vaccine response to the Omicron variant for interval between completion of primary course and booster vaccination, by JCVI advice for booster vaccination of those aged 12-15 in clinical risk groups plus those aged 16 and 17 years and by JCVI advice for fourth/fifth doses in eligible groups. 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. 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.
Storage	• Ensure within expiry date

requirements	• Comirnaty® 30 micrograms/dose COVID-19 mRNA Vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice • Once removed from the freezer Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine can be stored for 31 days in a fridge between +2 to +8°C prior to dilution • NHS Fife guidance on Storage and Handling of vaccines should be observed • Comirnaty® 30 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 6 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+6 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 NHS Fife Pharmacy should be contacted for risk assessment 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
Black Triangle Drug ▲	• Yes, Comirnaty® 30 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) has been designated ▼
Identification and management of adverse reactions	• Advise patients to seek medical advice for significant side effects or if concerned • Local reactions at the injection site are fairly common after Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) primarily pain at the injection site, usually without redness and swelling. Systemic events reported were generally mild and short lived In the final safety analysis of over 21,000 participants 16 years and older, the most common events were injection site pain (>80%), fatigue (>60%), and headache (>50%). Myalgia, arthralgia and chills were also common with fever in 10-20% mainly after the second dose. Most were classified as mild or moderate. Lymphadenopathy in the axillary, supraclavicular or cervical nodes on the same side as the injection was reported in less than 1%. Four cases of Bell's palsy were reported in vaccine recipients in the trial. Although within the expected background rate, this will be monitored closely post-implementation. • Side effects were less common in those aged over 55 than those aged 16 to 55 years. Severe systemic effects, defined as those that interfere with daily activity, included fatigue in around 4% and headache in 2%. There was no signal to suggest that prior vaccination led to enhanced disease with only 1 case of severe COVID-19 in the 8 vaccine failures. • 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 • All suspected serious reactions should be reported directly to the MHRA/Commission on Human Medicines through the Yellow Card scheme and recorded in the patient's medical notes. Reports should be made online at https://coronavirus-yellowcard.mhra.gov.uk/ • As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available • 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 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
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
Monitoring if required	• 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. • 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
Follow up	• N/A
Additional facilities/ supplies required	• Immediate access to anaphylaxis medication as appropriate to current NHS Fife procedure for the Management of Anaphylaxis • 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 • Immediate telephone access • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) should be followed • Adhere to hand decontamination policy

3. Staff characteristics

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) under this PGD: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • physiotherapists, chiropodists/podiatrists currently registered with the Health and Care Professions Council (HCPC) and who hold a recognised qualification in Injection Therapy • dental hygienists and dental therapists currently registered with the General Dental 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: a. demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine b. 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 • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy • have undertaken NHS Fife approved anaphylaxis management training • have undertaken NHS Fife approved training in adult basic life support • must be conversant with key issues in vaccine management (e.g. safe transport, maintaining cold-chain etc) in accordance with NHS Fife Policies • It is essential that the NHS Fife approved PGD e-learning programme is accessed and completed by NHS Fife employed staff • It is the responsibility of the designated authorised staff using this PGD to ensure that treatment with the vaccine detailed in the direction is appropriate. If in any doubt, advice should be sought and recorded before the vaccine is administered <u>Employer</u> • **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**
Continued training requirements	• 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 • Keep up-to-date with information on contraindications, cautions and interactions from the BNF, SPC and PIL and refer to a senior clinician if necessary • Annual update of anaphylaxis management according to NHS Fife Policy • Annual update of training adult basic life support • A 2 yearly update of the PGD e-learning programme for NHS Fife employees is essential

4. Referral arrangements/Audit trail

Arrangements for referral to medical advice	• The patient may be referred to a senior clinician at any stage, if this is necessary, in the professional opinion of the healthcare practitioner
Records/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 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
References/ Resources & comments	• NHS Fife Consent Policy • NHS Fife Procedure for the Management of Anaphylaxis • NHS Fife Resuscitation Guidelines • NMC/RPS Administration of Medicines Guidance Jan 2019 • NHS Fife Safe and Secure Use of Medicines Policy and Procedures (SSUMPP) • Summary of Product Characteristics – currently available at https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19?utm_source=5108b366-c820-4b37-bd46-11e483ba19f7&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate • 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 • 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 • All relevant Scottish Government advice including the relevant CMO letter(s)

This Patient Group Direction has been assessed for Equality and Diversity Impact

5. Management and monitoring of patient group direction

This patient group direction is to be read, agreed to, and signed by all registered healthcare practitioners it applies to.
One signed copy is to be given to each clinician with the original being kept on file by the line manager
One signed copy should be forwarded to the appropriate lead clinician.

Registered Healthcare Practitioner Agreement

I _____, confirm that I have read and understood the above Patient Group Direction. I confirm that I have the necessary professional registration, competence, and knowledge to apply the Patient Group Direction. I will ensure my competence is updated as necessary. I will have ready access to a copy of the Patient Group Direction in the clinical setting in which supply or administration of the medicine will take place.

I understand that it is the responsibility of the registered healthcare practitioners to act in accordance with the NMC Guidelines for Professional Practice and Guidelines (or Guidelines, / Code of Ethics of other Professional body) for the Administration (or Supply) of Medicines and to keep an up to date record of training and competency.

Name of clinician----------

Professional Category----------

Registration No.----------

Name & Contractor code HB – (Pharmacy/Dental/Optometry Only)

Please email a copy to: Fife.pgd@nhs.scot

Is authorised to give **Comirnaty® 30 micrograms/dose (COVID-19 mRNA Vaccine**, Pfizer/BioNTech) listed under this patient group direction

Place of Work----------

Signature of clinician----------

Date----------

Authorised by:

Name of authorising clinician/manager----------

Signature----------

Date----------

If this PGD is past its review date then the content will remain valid until such time as the PGD review is complete and the new issue published

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