NHS
Greater Glasgow and Clyde

Patient Group Direction (PGD) Template

Administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech

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

Publication date: 05 July 2021

PGD No: 2021/2178

Version history

Version	Date	Summary of changes
1.0	04/12/20	Version 1.0 new PGD
1.1	10/12/20	The following sections have been updated following the publication of updated COVID-19 –SARS-Cov-2 chapter 14a of Green Book and updated guidance from Medicines & Healthcare products Regulatory Agency on managing allergic reactions. • Inclusion criteria updated to include reference to Table 3 COVID-19 – SARS-Cov-2 chapter 14a of Green Book for individuals aged 16 years to 64 years with underlying health conditions. • Exclusion criteria updated to align with MHRA guidance that any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive COVID-19 mRNA Vaccine BNT162b2. • Frequency section updated to align with wording in chapter 14a of Green Book that scheduling the second dose of COVID-19 mRNA Vaccine BNT162b2 from 28 days after the first is may be preferred rather than is recommended. • Additional monitoring section updated to refer to MHRA Coronavirus Yellow Card Scheme. • Use out with the SPC section updated to align with wording in chapter 14a of Green Book that scheduling the second dose of COVID-19 mRNA Vaccine BNT162b2 from 28 days after the first is may be preferred rather than is recommended. • Additional information section updated to align with wording chapter 14a of Green Book for those with prolonged COVID-19 symptoms. • Warnings and ADR section updated to align with wording in chapter 14a of Green Book for adverse reactions to COVID-19 mRNA Vaccine BNT162b2

Version	Date	Summary of changes
		• Warnings and ADR section updated to align with MHRA guidance on anaphylaxis recognition and treatment. • Additional facilities section updated to align with MHRA guidance on anaphylaxis recognition and treatment. • Reporting ADR section updated to refer to MHRA Coronavirus Yellow Card Scheme. • Observation following vaccination section updated to align with MHRA guidance that vaccine recipients should be monitored for 15 minutes after vaccination
1.2	31/12/20	The following sections have been updated following the publication of updated advice from JCVI. • Indication section updated to include JCVI statement 30 December 2020 • Inclusion criteria updated to align with wording of JCVI statement 30 December 2020 • Exclusion criteria updated wording on pregnancy and history of anaphylaxis • Cautions section updated with additional wording on pregnancy and breastfeeding • Form/strength section updated with updated description of vaccine • Route of administration section updated with updated description of vaccine; advice on sixth dose and reference that preferred site of injection is the deltoid area of the upper arm. • Frequency section updated to reflect JCVI advice on scheduling second dose and that the second vaccine dose should be with the same vaccine as for the first dose. • Use out with the SPC section updated to reflect JCVI advice on scheduling second dose. • Advice to patient section updated to remove reference advice on avoiding pregnancy after vaccination.
1.3	28/01/21	The following sections have been updated • Exclusion section updated to align with wording in Green Book on previous systemic allergic reaction (including immediate-onset anaphylaxis and an additional exclusion for those patients with history of systemic reaction to biologics/monoclonals except on the advice of an allergy specialist.

Version	Date	Summary of changes
		• Cautions section updated to include advice from Green Book on second doses following non allergic reactions or localised urticarial skin reactions without systemic symptoms following first dose. • Form/strength section updated to reflect number of doses in a vial • Route of administration section updated to align with wording in information for UK health professionals on number of doses in a vial. • Frequency section updated to align with advice in Green Book on timing of second dose for those commencing immunosuppressive treatment. • Observation following vaccination section updated with advice on post vaccine observation of second doses in those who had localised urticarial skin rashes (without systemic symptoms to the first dose.
1.4	25/02/21	The following sections have been updated: • Inclusion section updated to include women who are pregnant where the risk of exposure to SARS-CoV2 infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19 and to remove statement not including pregnant women from clinically extremely vulnerable individuals • Exclusion section updated to remove pregnancy and evolving neurological conditions • Exclusion section updated to include prior allergic reaction to another mRNA vaccine and highlighting PEG specifically in the vaccine component. • Exclusion section updated to include those patient characteristics which warrant special precautions as per the Green Book. • Cautions section updated to include Management of patients with a history of allergy and Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine. • Action if excluded section updated to remove reference to evolving neurological conditions. • Frequency section updated to align with Green Book advice on scheduling of second dose.

Version	Date	Summary of changes
1.5	19/04/21	The following sections have been updated: • Indications section updated to include updated JCVI statements on priority groups • Inclusion section updated to include those aged from 18 years and adult household contacts of adults with severe immunosuppression • Inclusion section updated to align with JCVI advice on the use of vaccination in pregnancy. • Inclusion section updated to highlight the inclusion criteria refer to COVID-19 mRNA Vaccine BNT162b2 • Cautions section updated to enable the use of Moderna vaccine in pregnant and breastfeeding women. • Cautions section updated to align with JCVI advice on the use of vaccination in pregnancy. • Frequency section updated to reflect JCVI advice on intervals between doses • Warnings section updated to align with Green Book Chapter. • Reference section updated to include JCVI advice on phase 2 priority groups
1.6	10/05/21	The following sections have been updated: • Inclusion section updated to include those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated. • Exclusion section updated to include 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). • Caution section updated to remove reference to AstraZeneca vaccine. • Frequency section updated to remove advice that the second vaccine dose should be with the same vaccine as for the first dose.
1.7	24/05/21	The following sections have been updated:

Version	Date	Summary of changes
		• Frequency section updated to include JCVI advice that second doses of all vaccines should be brought forward from 12 to 8 weeks for all priority groups, with priority given to those areas where the B.1.617.2 variant is of the highest threat. • Storage requirements section updated to include updated information storage of vaccine after removal from the freezer.
1.8	25/06/21	The following sections have been updated: • Inclusion criteria section updated to include all eligible adults over 16 in line with JCVI recommendations on or before 31 July 2021
1.9	05/07/21	The following sections have been updated: • Cautions section updated to align with Green Book chapter on co-administration with other vaccines. • Frequency section updated to align with Green Book chapter advice on scheduling. • Frequency section updated to align with Green Book chapter on interchangeability between COVID-19 vaccines. • Duration of treatment section updated to align with Green Book chapter on reinforcing immunisation. • Use out with the SPC section updated with Green Book chapter advice on scheduling.

Contents

Effective from: 05/07/2021 **Review date:** 30/11/2021

Clinical situation

Category	Description
Indication	COVID-19 mRNA Vaccine BNT162b2 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', JCVI statement on priority groups for COVID-19 vaccination from 30th December 2020. JCVI statement on phase 2 of the vaccination programme from 13th April 2021 and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. COVID-19 mRNA Vaccine BNT162b2 should be offered to the following individuals: • Residents in a care home for older adults and their carers • All those 80 years of age and over • Frontline health and social care workers (as included in COVID-19 –SARS-Cov-2 chapter of Green Book, JCVI statement and Scottish Government CMO letters) • All those 75 years of age and over • All those 70 years of age and over • Clinically extremely vulnerable (CEV) individuals (not including those under 16 years) as defined by Scottish Government at **https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/** • All those 65 years of age and over • Individuals aged 16 years to 64 years with underlying health conditions which puts them at higher risk of serious disease and mortality included in Table 3 COVID-19 –SARS-Cov-2 chapter 14a of Green Book* this also includes adult household contacts of adults with severe immunosuppression • All those 60 years of age and over • All those 55 years of age and over • All those 50 years of age and over • All those 40 years of age and over • All those 30 years of age and over • All those aged 18 years to 29 years • All eligible adults over 16 in line with JCVI recommendations on or before 31 July 2021

Category	Description
	• Pregnant women should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age, because of more extensive experience of their use in pregnancy. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. • Those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated. *This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. The list above is not exhaustive, and clinician should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself. COVID-19 vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above, this may be provided under a Patient Specific Direction (PSD).
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of this COVID-19 vaccine • Those who have had a prior allergic reaction to another mRNA vaccine e.g. Moderna COVID-19 vaccine. • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any component (excipient) of the COVID-19 vaccine 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 has been received • Those who are under 16 years of age

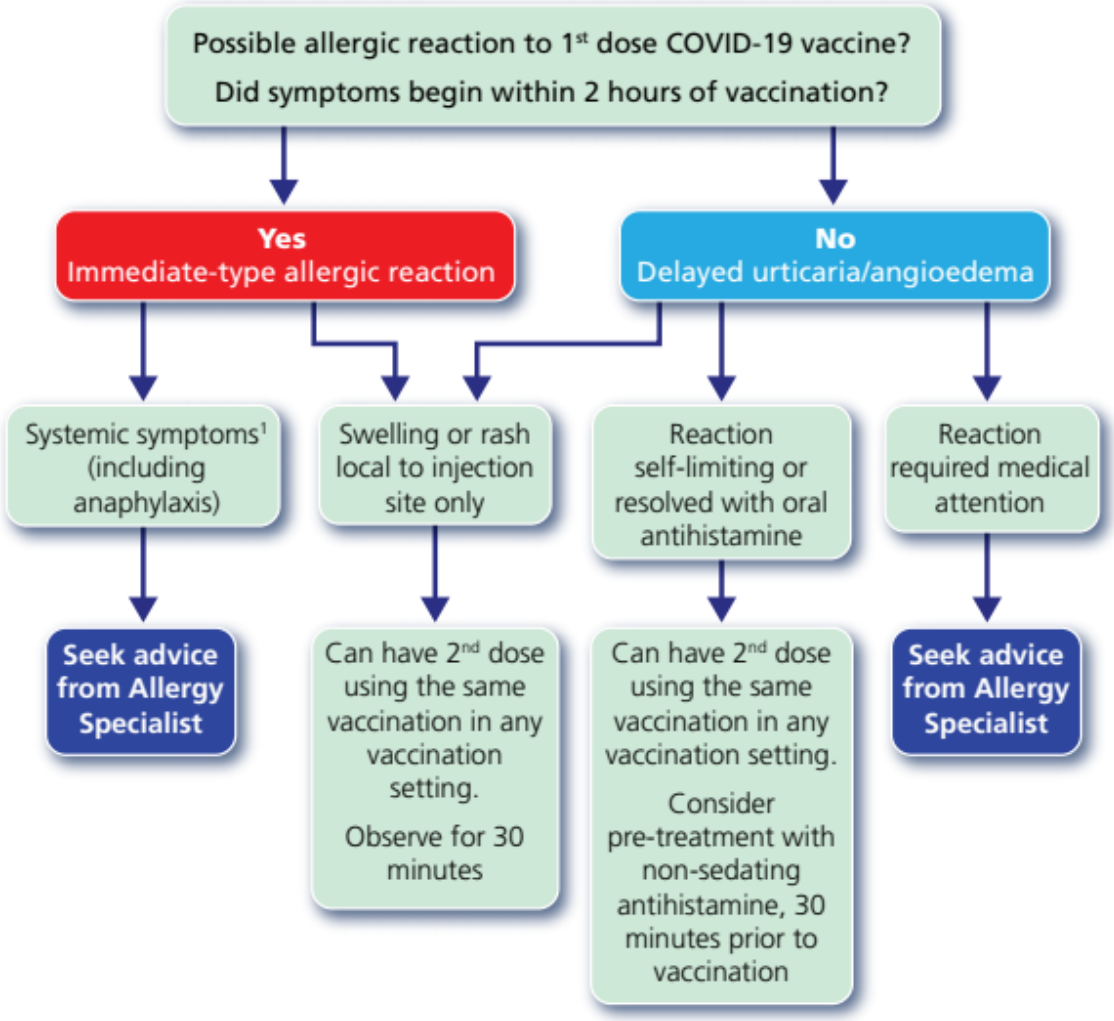
Category	Description
	• Those with confirmed COVID-19 infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic. • 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 who are participating in a clinical trial of COVID-19 vaccines • 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.
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. The 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. It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine. Figure 1 summarises the management of patients with a history of allergy. **Appendix 1** provides an accessible version of Figure 1. **Figure 1: Management of patients with a history of allergy**

Category	Description

	Proceed with vaccination	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) • family history of allergies • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• 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 systemic allergic reaction to the COVID-19 vaccine • for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine • prior allergic reaction to a component of the vaccine, including PEG
ACTIONS	• proceed with vaccination as normal, according to local guidelines	• discuss with allergy specialist and consider possibility of PEG-allergy • consider observation for 30 minutes if vaccination proceeds (see precautions) • some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction	• do not give vaccine in question • refer to allergist

Figure 2 shows the Green 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
	 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. Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). 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 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. 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 reduce the response to the live virus. 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,

Category	Description
	paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. 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 woman or the unborn child. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. 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 women. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.
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. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. In case of postponement due to COVID-19 symptoms or positive COVID test in the last four weeks 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. 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	COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection
Form/strength	COVID-19 mRNA Vaccine BNT162b2 30micrograms/0.3ml dose concentrate for solution for injection multidose vials COVID-19 mRNA Vaccine BNT162b2 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 BNT162b2 RNA (embedded in lipid nanoparticles).
Route of administration	After dilution, vials of COVID-19 mRNA Vaccine BNT162b2 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. COVID-19 mRNA Vaccine BNT162b2 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 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.

Category	Description
	The site at which each vaccine was given should be noted in the individual's records.
Dosage	The dose of COVID-19 mRNA Vaccine BNT162b2 is 30 micrograms contained in 0.3mL of the diluted vaccine.
Frequency	COVID-19 mRNA Vaccine BNT162b2 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 are used. Currently, JCVI is recommending an interval of 8 to 12 weeks between doses of all the available COVID-19 vaccines. Operationally, this consistent interval should be used for all two dose vaccines to avoid confusion and simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. The main exception to the eight week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined below may be followed to ensure that the vaccine is 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. If an interval longer than the recommended interval is left between doses, 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. Evidence from trials of co-administration suggest 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 at the second dose are higher. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. Further doses would not then be required.

Category	Description
Duration of treatment	See Dose and frequency of administration above. The need for booster doses is still under consideration by JCVI as the need for, and timing of boosters has not yet been determined.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 30 micrograms in 0.3mL per administration.
▼ black triangle medicines	COVID-19 mRNA Vaccine BNT162b2 did not have a UK marketing authorisation at the time this PGD was written and is authorised for temporary supply in the UK in accordance with a Regulation 174 authorisation. 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	COVID-19 mRNA Vaccine BNT162b2 is provided temporary authorisation by the Medicines & Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A, pending UK marketing authorisation. The regulation 174 authorised product is categorised as a prescription only medicine (POM).
Is the use out with the SPC?	COVID-19 mRNA Vaccine BNT162b2 is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this PGD. As part of the consent process, inform the individual/carer that this vaccine does not have a UK marketing authorisation but has been authorised for temporary supply in the UK by the MHRA and that it is being offered in accordance with national guidance. The vaccine manufacturer's information for UK healthcare professionals 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 advice that the second dose of both vaccines should be routinely scheduled between eight and 12 weeks after the first dose.
Storage requirements	COVID-19 mRNA Vaccine BNT162b2 must be stored frozen at ultra-low temperature in accordance with manufacturer's advice. Once removed from the freezer BNT162b2 vaccine can be stored for 31 days in a fridge between +2 to +8°C prior to dilution.

Category	Description
	NHS Board guidance on Storage and Handling of vaccines should be observed. COVID-19 mRNA Vaccine BNT162b2 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 +25°C. The vaccine vial has space to write the date and time of dilution; 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 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. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic. 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 management of these	Local reactions at the injection site are fairly common after COVID-19 mRNA Vaccine BNT162b2, 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 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. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever COVID-19 mRNA Vaccine BNT162b2 is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml 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.

Category	Description
	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 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 • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years 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 unless the individual has other COVID-19 symptoms; has been told by NHS Test and Protect they are a close contact of someone who has tested positive for COVID-19; they live with someone who has recently tested positive for COVID-19; or they live with someone who has symptoms of COVID-19. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should self-isolate and book a 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.

Category	Description
	• As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24 • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk. • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection. • When administration is postponed advise the individual how future vaccination may be accessed • When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Observation following vaccination	Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. 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. Individuals with swelling or a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in any setting.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever COVID-19 mRNA Vaccine BNT162b2 is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml 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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer COVID-19 mRNA Vaccine BNT162b2 • 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: 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

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 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

NHS Greater Glasgow & Clyde Patient Group Direction (PGD) for Health Care Professionals
COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech

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** JCVI: advice on priority groups for COVID-19 vaccine 30th December 2020 **https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020** JCVI: Final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 JCVI final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 **https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi** 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 Scottish Government advice including the relevant CMO letter(s)

Organisation:	**NHS Greater Glasgow & Clyde**
Professionals drawing up PGD/Authors	
	Designation and Contact Details
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Na me: Hilda Crookshanks  Signature: Date: 09/07/2021	Designation: Health Protection Nurse Specialist, Public Health Protections, West House, NHS GG&C E-mail address: Hilda.crookshanks@ggc.scot.nhs.uk
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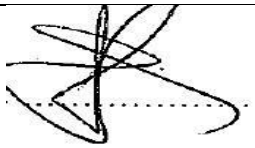
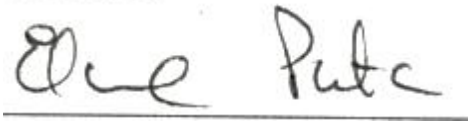
AUTHORISATION

NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**09/07/2021**

NHSGG&C PGD Sub-Committee of ADTC		
Lead Nurse, North Sector, NHS GG&C in BLOCK CAPITALS	**Signature:**	**Date:**
John Carson		**09/07/2021**

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**09/07/2021**

PGD for administration of COVID-19 mRNA Vaccine BNT162b2 PGD v1.9 Valid from: 05/07/2021 Expiry: 30/11/2021 - authorisation

Practitioner

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

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it. I agree to administer COVID-19 mRNA Vaccine BNT162b2 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	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) • family history of allergies • previous non-systemic reaction to a vaccine • hypersensitivity to nonsteroidal antiinflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• history of immediate anaphylaxis to multiple different drug classes, with the trigger unidentified (this may indicate a 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 systemic allergic reaction to the COVID-19 vaccine • for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine • prior allergic reaction to a component of the vaccine, including PEG
Actions	• proceed with vaccination as normal, according to local guidelines	• discuss with allergy specialist and consider possibility of PEG allergy • consider observation for 30 minutes if vaccination proceeds (see precautions – **p17 in Green Book COVID-19 chapter 14a**) • some patients may benefit from pre-treatment with antihistamine, however this may mask initial symptoms of a reaction	• do not give vaccine in question • refer to allergist