

**Patient Group Direction For The Administration Of COVID-19 mRNA Vaccines To Individuals Aged Under 18 Years By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles**

<b>Lead Author:</b> Adapted from Public Health Scotland Administration of COVID-19 mRNA vaccines to individuals aged under 18 years Patient group direction (PGD) template, Version 3.1 – Published 13 <sup>th</sup> March 2024		<b>Approver:</b> NoS PGD Group  <b>Authorisation:</b> NHS Grampian
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<b>NoS Identifier:</b> NoS/PGD/ COVID19_Vaccine_U18/ 1479	<b>Review Date:</b> 31 <sup>st</sup> August 2024  <b>Expiry Date:</b> 31 <sup>st</sup> August 2024	<b>Date Approved by NoS:</b> March 2024
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NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

**Uncontrolled when printed**  
  
**Version 3.1**

### Revision History for NoS:

<b>NoS PGD that has been superseded</b>	NOS/PGD/COVID19_Vaccine_U18/1409
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### Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
3.0	12 March 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
3.0	19 March 2024	Not Issued	
3.1	19 March 2024	Summary minor amendment	

## Most recent changes

Version	Date	Summary of changes
3.0	1 March 2024	<p>The following changes to version 2.1 of the PGD have been made:</p> <ul style="list-style-type: none"> <li>PGD updated to reference mRNA vaccines only.</li> <li>PGD updated to remove reference to bivalent Original/Omicron BA. 4-5 vaccines.</li> <li>Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book <b>Chapter 14a</b>, and/or in line with subsequent correspondence/publications from Scottish Government.</li> <li>Inclusion criteria, frequency, is the use out with the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.</li> </ul>

Version	Date	Summary of changes
		<ul style="list-style-type: none"> <li>• Frequency section updated to reflect updated Green Book Chapter advice for Spring 2024 programme and for severely immunosuppressed individuals.</li> <li>• Is the use out with the SmPC and observation following vaccination sections updated to remove advice from Scottish Government on 5 minute wait.</li> </ul>
3.1	19 March 2024	Minor typographical changes to recent changes section to correct previous version numbers

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

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## Authorisation

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


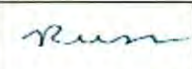
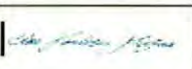
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer Administration of COVID-19 vaccines to individuals aged under 18 years under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD.


NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the COVID-19 vaccines to individuals aged under 18 years has to be by the same practitioner who has assessed the patient under the PGD.

All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines under PGD ([Appendix 1](#)).

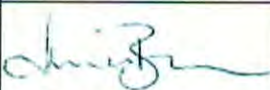
A Certificate of Authorisation ([Appendix 2](#)) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.

This PGD has been produced for NoS by:					
Doctor	Dr Susan Laidlaw	Signature		Date Signed	15/03/2024
Pharmacist	Russell Mackay	Signature		Date Signed	20/03/2024
Nurse	Claire Henderson - Hughes	Signature		Date Signed	15/03/2024

#### Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		20/03/2024

#### Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells - Interim Chief Executive PP: June Brown, Executive Nurse Director		21/03/2024

#### Version 3.1 – Approved for NoS 21<sup>st</sup> March 2024

# 1. Clinical situation

## 1.1. Indication

COVID-19 mRNA vaccines are indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in those aged under 18 years in accordance with Scottish Government COVID-19 immunisation programme and JCVI advice/recommendations as set out in Green Book [Chapter 14a](#) and subsequent correspondence/publications from Scottish Government.

## 1.2. Inclusion criteria

COVID-19 mRNA vaccines should be offered to individuals aged under 18 years invited, or eligible in accordance with the recommendations in Green Book Chapter 14a, and/or in line with subsequent correspondence/publications from Scottish Government.

National policy must be followed in relation to the groups eligible for vaccination at a particular point in time including vaccination for travel entry certification and ad-hoc occupational purposes internationally.

Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the [Scottish Haematology Society Revaccination Schedule](#).

Valid consent has been given to receive the vaccine.

## 1.3. Exclusion criteria

Individuals who:

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

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

Some COVID-19 vaccines are restricted to use in particular age groups. Practitioners must be familiar with and refer to the marketing authorisation holder's SmPC for the particular vaccine.

- **Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine** is recommended for those aged 12-17 years
- **Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine** is recommended for those aged 5-11 years
- **Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA vaccine** is recommended for those aged six months-4 years

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

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

### Individuals with a history of allergy

Those with a personal history of allergy should be managed in line with table 5, Green Book, **Chapter 14a**.

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

Green Book **Chapter 14a** states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended.

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

## Individuals with thrombocytopenia

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

## Guillain-Barré syndrome (GBS)

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

## Individuals with a bleeding history

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

## Co-administration with other vaccines

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

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

## Syncope

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

## Pregnancy and breastfeeding



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.

Vaccination in pregnancy should be offered in accordance with recommendations in Green Book **Chapter 14a**, following a discussion of the risks and benefits of vaccination with the woman.

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

## **Clinical trial participants**

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

## **Individuals with a past history of COVID-19 infection**

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

Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness although individuals with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting others.

There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms, whether or not they are tested for COVID-19.

## **1.5. Action if excluded**

Specialist advice must be sought on the vaccine and circumstances under which it could be given. Immunisation using a patient specific direction may be indicated. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in accordance with local procedures.

Inform or refer to the clinician in charge.

## Temporary exclusion

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

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

## 1.6. Action if patient declines

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

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

Document advice given and decision reached.

Inform or refer to the clinician in charge.

## 2. Description of treatment

### 2.1. Name of medicine/form/strength

Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine dispersion for injection multi dose vial. Multidose vial that contains 6 doses of 0.3 ml. One dose (0.3 ml) contains 30 micrograms of raxtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine dispersion for injection multi dose vial. Multidose vial that contains 6 doses of 0.3 ml. One dose (0.3 ml) contains 10 micrograms of raxtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

Comirnaty Omicron XBB.1.5 (3micrograms/dose) concentrate for dispersion for injection COVID-19 mRNA vaccine dispersion for injection multi dose vial. Multidose vial which **must** be diluted with 2.2ml of 0.9% sodium chloride before use. After dilution each vial contains 10 doses of 0.2 ml. One dose (0.2 ml) contains 3 micrograms of raxtozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

## 2.2. Route of administration

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

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled international normalised ratio (INR) blood-clotting testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.

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

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

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

## 2.3. Dosage

- Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine dose in 0.3ml
- Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine dose is 0.3ml
- Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA vaccine dose is 0.2ml of the diluted vaccine.

## 2.4. Frequency

### Individuals aged 12-17 years

A single dose of Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine dose regardless of prior COVID-19 vaccination status.

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

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

## **Individuals aged 5-11 years**

A single dose of Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine regardless of prior COVID-19 vaccination status.

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

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

## **Individuals aged six months to 4 years**

### **Primary immunisation**

Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA primary vaccine course consists of two separate doses of 0.2ml each, a minimum of 12 weeks apart.

In those who have already received one previous dose of COVID-19 vaccination a single dose of Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA vaccine dose, should be given at least three months (12 weeks) after any previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose) to complete the primary course.

### **Reinforcing dose**

For those who have previously received primary vaccination a single dose of Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA. The dose should be given at least three months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose).

## Individuals identified as meeting the definition for severe immunosuppression

Additional doses for those identified as meeting the definition for severe immunosuppression (as defined in Green Book [Chapter 14a](#)) may be required.

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

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

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

Clinical judgement should be used to decide which individuals should be given an additional dose soon after their diagnosis rather than waiting for the next campaign and thus getting extra protection during the season, particularly over the winter, and at the same time as other high risk groups. The optimal timing should also take account of the degree of immune suppression (see Green Book [Chapter 14a](#) section on timing). Second doses should ideally be given between 8-12 weeks from the previous dose, to extend protection. This interval may be reduced to three weeks on specialist clinical advice to maximise short term protection, bearing in mind that response may be less durable. As above, subsequent doses may be optimally delivered during the next regular campaign.

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

Additional doses are covered by this PGD.

## Revaccination of individuals who have received a haemopoietic stem cell transplant

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

## 2.5. Duration of treatment

See frequency section.

## 2.6. Maximum or minimum treatment period

See frequency section.

## 2.7. Quantity to supply/administer

See frequency section.

## 2.8. ▼ black triangle medicines

Yes.

All COVID-19 vaccines are subject to additional monitoring and are designated as ▼.

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

## 2.9. Legal category

Prescription only medicine (POM).

## 2.10. Is the use outwith the SmPC?

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

The vaccine marketing authorisation holder's SmPC states that a primary course for those aged six months to four years of age consists of three doses. This is superseded by JCVI advice for a two dose primary schedule as set out in Green Book **Chapter 14a**.

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

## 2.11. Storage requirements

### General requirements

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

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

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

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

### Vaccine specific requirements

#### **Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine**

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

After first use – use as soon as practically possible and within 12 hours. The vaccine can be stored at +2°C to +30°C during the in-use time. Thawed vials can be handled in room light conditions.

The vaccine vial has space to write the date and time that the vial should be discarded following first puncture; write this on the vial label.

#### **Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine**

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

After first use – use as soon as practically possible and within 12 hours. The vaccine can be stored at +2°C to +30°C during the in-use time. Thawed vials can be handled in room light conditions.

The vaccine vial has space to write the date and time that the vial should be discarded following first puncture; write this on the vial label.

## **Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA vaccine**

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

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

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

### **2.12. Additional information**

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

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

Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

## **3. Adverse reactions**

### **3.1. Warnings including possible adverse reactions and management of these**

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

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

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



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

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

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

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

### 3.2. Reporting procedure for adverse reactions

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

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

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

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

### 3.3. Advice to patient or carer including written information

Written information to be given to individual:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.

- 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 when appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management.
- Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required.
- Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection.
- Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment, but paracetamol can be taken if necessary to relieve any of these symptoms. Aspirin should not be given to those under 16 years of age.
- Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently:
  - chest pain
  - shortness of breath
  - feelings of having a fast-beating, fluttering, or pounding heart
- As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24.
- The individual should be advised to seek medical advice in the event of a severe adverse reaction.
- Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on:  
<http://www.mhra.gov.uk/yellowcard>.
- 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.

### 3.4. Observation following vaccination

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

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

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

Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.

### 3.5. Follow up

Not applicable.

### 3.6. Additional facilities

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

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

## 4. Characteristics of staff authorised under the PGD

### 4.1. Professional qualifications

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

- nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- dental hygienists and dental therapists registered with the General Dental Council.
- optometrists registered with the General Optical Council.

### 4.2. Specialist competencies or qualifications

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

All practitioners operating this PGD:

- demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine.
- have met the requirements of the NES Proficiency document -COVID-19 vaccine administration for registered staff or the NES Proficiency document – COVID-19 vaccine administration. This NES Proficiency document can be found at TURAS Learn at:  
<https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines>

All persons operating this PGD:

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

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

## Employer

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

## 4.3. Continuing education and training

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

Have undertaken NoS PGD module training on **TURAS Learn**

- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements.
- Have undertaken immunisation training where available.
- Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements.
- Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

## 5. Audit trail

**Record the following information:**

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

Records should be kept in line with local procedures.

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

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

## 6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book].**
- **Immunisation against Infectious Disease [Green Book] COVID-19**
- **Comirnaty Omicron XBB.1.5 (30micrograms/dose) COVID-19 mRNA vaccine Summary of Product Characteristics**
- **Comirnaty Omicron XBB.1.5 (10micrograms/dose) COVID-19 mRNA vaccine Summary of Product Characteristics**

- **Comirnaty Omicron XBB.1.5 (3micrograms/dose) COVID-19 mRNA vaccine Summary of Product Characteristics**
- **Educational resources for registered professionals produced by National Education for Scotland**
- All relevant JCVI statements.
- All relevant Scottish Government advice including the relevant CMO letter(s).
- **Scottish Haematology Society Advice on the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment**

## 7. Version history

Version	Date	Summary of changes
1.0	1 September 2023	Version 1.0 New PGD
2.0	14 September 2023	<ul style="list-style-type: none"> <li>Updated throughout to include XBB.1.5 variant vaccines.</li> <li>Cautions section updated to remove deferral for two weeks after COVID-19 infection.</li> <li>Frequency section updated to align with Green Book chapter advice on additional doses for those identified as meeting the definition for severe immunosuppression.</li> <li>Use outwith SmPC – updated following change in SmPC for Comirnaty BA4.5 and minor changes to wording on post vaccination observation.</li> <li>Observation following vaccination section - minor changes.</li> </ul>
2.1	18 September 2023	<ul style="list-style-type: none"> <li>Section 2.1 updated to highlight that Comirnaty Omicron XBB.1.5 (3micrograms/dose) is a concentrate for dispersion for injection which requires dilution before use.</li> <li>Section 2.3 (dosage) updated to highlight at dose of Comirnaty Omicron XBB.1.5 (3micrograms/dose) is 0.2ml of diluted vaccine.</li> <li>Section 2.11 (storage) updated to include recommendations on storage of vaccine after dilution.</li> </ul>
2.2	3 October 2023	<ul style="list-style-type: none"> <li>Section 2.4 Frequency section updated for Individuals aged six months to 4 years</li> </ul>
3.0	1 March 2024	<p>The following changes to version 2.1 of the PGD have been made:</p> <ul style="list-style-type: none"> <li>PGD updated to reference mRNA vaccines only.</li> <li>PGD updated to remove reference to bivalent Original/Omicron BA. 4-5 vaccines.</li> <li>Inclusion criteria amended to include individuals invited, or eligible in accordance with the recommendations in Green Book <b>Chapter 14a</b>,</li> </ul>

Version	Date	Summary of changes
		<p>and/or in line with subsequent correspondence/publications from Scottish Government.</p> <ul style="list-style-type: none"> <li>• Inclusion criteria, frequency, is the use outwith the SmPC and additional reference sections updated to include reference to the Scottish Haematology Society schedule for the revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment.</li> <li>• Frequency section updated to reflect updated Green Book Chapter advice for Spring 2024 programme and for severely immunosuppressed individuals.</li> <li>• Is the use outwith the SmPC and observation following vaccination sections updated to remove advice from Scottish Government on 5 minute wait.</li> </ul>
3.1	19 March 2024	Minor typographical changes to recent changes section to correct previous version numbers

### Version history NoS

Version	Date of change	Summary of Changes	Section heading
1.0	1 September 2023	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
2.0	14 September 2023	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
2.1	21 September 2023	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training
3.0	12 March 2024	Reference to NoS Appendix 1 and 2	Authorisation



		Training requirements for NoS	Continuing education and training
3.0	19 March 2024	Not issued.	
3.1	19 March 2024	Minor amendment.	



## Appendix 1 - Healthcare Professional Agreement To Administer Medicine(s) Under Patient Group Direction

I: \_\_\_\_\_ (Insert name)

Working within: \_\_\_\_\_ e.g. Area, Practice

Agree to supply/administer the medicine(s) contained within the following Patient Group Direction:

### **Patient Group Direction For The Administration Of COVID-19 mRNA Vaccines To Individuals Aged Under 18 Years By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 3.1**

I have completed the appropriate training to my professional standards enabling me to supply/administration the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Profession: \_\_\_\_\_

Professional Registration number/PIN: \_\_\_\_\_



**Appendix 2 - Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction**

**The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

**The Senior Nurse/Professional** who approves a healthcare professional to supply/administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

**The Healthcare Professional** that is approved to supply/administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply/administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.

**Patient Group Direction For The Administration Of COVID-19 mRNA Vaccines To Individuals Aged Under 18 Years By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 3.1**

**Local clinical area(s) where the listed healthcare professionals will operate under this PGD:**

<b>Name of Healthcare Professional</b>	<b>Signature</b>	<b>Date</b>	<b>Name of Manager</b>	<b>Signature</b>	<b>Date</b>

