Public Health Scotland

Administration of Bimervax® LP.8.1 (Hipra Human Health COVID-19 vaccine [recombinant, adjuvanted]) vaccine

Patient group direction (PGD) template

Publication Date: 24th September 2026

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PGD Number: 2026/2979

Version 1.0



Translations and other formats are available on request at:

phs.otherformats@phs.scot

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Most recent changes

Version	Date	Summary of changes
1.0	24 September 2026	New PGD template to support delivery of the Autumn 2026 COVID-19 vaccination programme to eligible individuals aged 12 years and over. This template replaces the previous Nuvaxovid JN.1 V3.1 PGD template.

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Authorisation

PGD Bimervax® LP.8.1 (COVID-19 vaccine [recombinant, adjuvanted]) vaccine

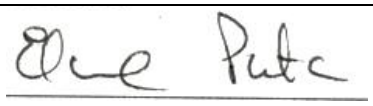
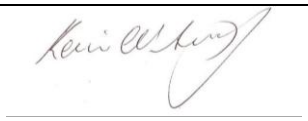
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer Bimervax® LP.8.1 (COVID-19 Vaccine (recombinant, adjuvanted)) under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the manufacturer's product information/Summary of Product Characteristics (SmPC) for all vaccines administered in accordance with this PGD. NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD.

This PGD has been produced for NHS Greater Glasgow & Clyde by:

Professionals drawing up PGD/Authors	
*Name: Sarah Marshall  Signature: Date: 29/09/2026	Designation: Specialist Pharmacist Public Health E-mail address: **sarah.marshall4@nhs.scot**
Name: Tina McMichael  Signature: Date: 20/09/2026	Designation: Health Protection Nurse Specialist E-mail address: **tina.mcmichael2@nhs.scot**
Name: Iain Kennedy  Signature: Date: 20/09/2026	Designation: Consultant in Public Health E-mail address: **iain.kennedy5@nhs.scot**

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

Chair	Dr Craig Harrow	
Director of Pharmacy representative	Elaine Paton, Senior Prescribing Adviser	
Director of Nursing Representative	Kevin McAuley, Chief Nurse North Sector	

Date approved: 29th September 2026

Effective from: 24th September 2026 Expiry date: 30th April 2027

1. Clinical situation

1.1. Indication

Bimervax® LP.8.1 (COVID-19 vaccine (recombinant, adjuvanted)) vaccine is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme, JCVI advice/recommendations given in **The Green Book COVID-19 Chapter** and subsequent correspondence/publications from **Scottish Government**.

1.2. Inclusion criteria

Individuals who:

- are aged 18 years and over invited, or eligible in accordance with the recommendations in **The Green Book COVID-19 Chapter**, and/or in line with subsequent correspondence/publications from **Scottish Government** and where mRNA vaccine is not available or supplied.

- are aged from 12 years where mRNA products are considered **not** clinically suitable.

Individuals who have received a haematopoietic stem cell transplant or CAR-T therapy and who require revaccination, in accordance with the **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment** guidance.

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 non mRNA COVID-19 vaccine.
- have had a confirmed anaphylactic reaction to any component of the vaccine or residual products from manufacture. Practitioners must check the marketing authorisation holder's SmPC for details of vaccine components.
- are under 12 years of age.
- 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 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.

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

1.4. Cautions/need for further advice/circumstances when further advice should be sought

The Green Book COVID-19 chapter 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

Bimervax® LP.8.1 vaccine does **not** contain PEG but does contain a related compound called polysorbate 80. Rarely, people with PEG allergy may also be allergic to polysorbate 80.

Those with a personal history of allergy should be managed in line with **The Green Book COVID-19 Chapter**.

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

The Green Book COVID-19 Chapter 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

For individuals with a history of idiopathic thrombocytopenic purpura (ITP) receiving any COVID-19 vaccine, checking their platelet count should be considered 2 to 5 days post vaccination. Individuals who previously experienced ITP after the first dose of AstraZeneca® vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which COVID-19 vaccine should be considered on an individual basis.

Guillain-Barré syndrome (GBS)

Very rare reports have been received of GBS following COVID-19 vaccination. Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment.

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.

Co-administration with other vaccines

Where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes, but is not limited to, vaccines commonly administered around the same time or in the same settings. Examples include LAIV, HPV, influenza, MenACWY and Td-IPV vaccines in the school age programmes, influenza, RSV and pertussis in pregnancy and influenza, pneumococcal, shingles and RSV vaccines in adults.

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

There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breastfeeding. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or the foetus.

Vaccination in pregnancy should be offered in accordance with recommendations in **The Green Book COVID-19 Chapter** 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 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.

Individuals who have received COVID-19 vaccine vaccinated overseas or as part of clinical trials

Eligible individuals who have been vaccinated abroad or in clinical trials should be offered COVID-19 vaccination in accordance with current recommendations. It is not necessary to know which vaccines an individual has previously received unless they indicate that they had an adverse event to a COVID-19 vaccine that would either contradict or be a precaution for a further dose. Specific advice is available from **UKHSA.**

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.

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.

During care home outbreaks, vaccination of residents with confirmed COVID-19 may go ahead provided the residents are clinically stable and infection control procedures can be maintained.

1.5 Action if excluded

Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated. 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 illness or COVID-19 symptoms, advise when the individual can be vaccinated. Ensure another appointment is arranged or the individual knows how future vaccination may be accessed.

1.6. Action if patient declines

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

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

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

Bimervax® LP.8.1 emulsion for injection COVID-19 Vaccine (recombinant, adjuvanted).

Single dose vial which contains 1 dose of 0.5 ml.

A 0.5ml dose contains 40 micrograms of SARS-CoV-2 virus recombinant spike (S) protein receptor binding domain (RBD) fusion homodimer (Omicron LP.8.1 – LP.8.1 strain) adjuvanted with SQBA.

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 or carer should be informed about the risk of haematoma from the injection.

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

0.5ml

An overfill is included in each vial to ensure that a 0.5 mL dose can be extracted.

Discard any remaining vaccine in the vial after a 0.5 mL dose has been extracted in accordance with local procedures.

2.4. Frequency

A single 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 3 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 3 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 3 weeks on specialist clinical advice.

Individuals anticipating immunosuppressive therapy

Individuals anticipating immunosuppressive therapy who have been assessed as eligible for COVID-19 vaccine and referred by their clinician for vaccination before starting treatment, should be offered vaccination in line with correspondence/publications from **Scottish Government**. Administration is permitted under this PGD.

Individuals identified as meeting the definition for severe immunosuppression

Additional doses for those identified as meeting the definition for severe immunosuppression (as defined in **The Green Book COVID-19 Chapter)** may be required.

From Autumn 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 3 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 **The Green Book COVID-19 Chapter** section on timing). Second doses should ideally be given between 8 to 12 weeks from the previous dose, to extend protection. This interval may be reduced to 3 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 haematopoietic stem cell transplant or CAR-T treatment

In accordance with the schedule recommended by the **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment guidance.**

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.

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?

For individuals who have previously been vaccinated with a COVID-19 vaccine, the SmPC states that Bimervax® LP.8.1 should be administered at least 6 months after the most recent dose of a COVID-19 vaccine. Reducing the dose interval to at least 3 months (12 weeks) after the previous dose of COVID-19 vaccine (regardless of the vaccine given for the previous dose) is out with the marketing authorisation holder's SmPC but in line with official recommendations see **The Green Book COVID-19 Chapter**).

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 (in 2021), 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 has since been extended to all currently available COVID-19 vaccines when used in the NHS programme.

Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment is considered off-label but is in accordance with the **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment guidance.**

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual, parent or carer that the vaccine is being offered in accordance with national guidance but this is outside of the product license.

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 NHS Board guidance on storage and handling of vaccines. 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 vials are stored in the outer carton in order to protect from light.

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

Vaccine should be stored at a temperature of +2° to +8°C.

Do not freeze.

2.12. Additional information

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

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

Common and very commonly reported adverse reactions are detailed below. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination.

Table 1. Summary of common and very common adverse reactions for COVID-19 vaccines

Vaccine	Very Common	Common
Bimervax® LP.8.1	headache, myalgia, injection site pain, fatigue	lymphadenopathy, diarrhoea, vomiting, nausea, injection site swelling, erythema and induration, pyrexia, axillary pain

Injection site induration, malaise, axillary pain and arthralgia occurred at higher frequencies in adolescents compared to adults, with the frequency being very common in adolescents.

Very rare cases of myocarditis and pericarditis have been observed following COVID-19 vaccination. The reported rate is highest in individuals under 25 years and in males, usually within a few days following vaccination, after a second dose. Most cases are mild and self-limiting. The MHRA has advised the benefits from vaccination outweigh any risk in most individuals. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Recipients, and if appropriate parents and carers, 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.

Lymphadenopathy: Swollen axilla or neck glands on the same side as the vaccination site can occur as a common reaction, which can last for up to 10 days. If the vaccine recipient is due to attend for a mammogram, they should be advised to inform clinicians regarding date of vaccine administration.

As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.

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

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

For full details/information on possible side effects, refer to the marketing authorisation holder's 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. **The Green Book Vaccine safety and adverse events following immunisation 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 **The Green Book Vaccine safety and adverse events following immunisation 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, parent or carer:

- Provide manufacturer’s consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Immunisation promotional material may be provided as appropriate.

Individual advice / follow up treatment:

- Inform the individual, parent or carer of possible side effects and their management.
- Inform the individual, parent or 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**

- As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine.

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

3.4. Observation following vaccination

Following immunisation, patients remain under observation in line with NHS Board policy.

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.

Syncope (fainting) can occur following vaccination. Some of the adverse effects and syncope may temporarily affect the ability to drive or use machines. It is advised not to drive or use machinery until the prevailing symptoms have cleared. Where relevant, 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 **The Green Book COVID-19 Chapter**.

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

As above.

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)
- pharmacy technicians 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 Public Services Delivery Scotland (PSDS), Proficiency Document for Administration of Vaccines by Registered Healthcare Practitioners and COVID-19 vaccination core eLearning.

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/ SmPC information.
- must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent.
- must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions.
- must have access to the PGD and associated online resources.
- should fulfil any additional requirements defined by local policy.

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

Employer

The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD.

As a minimum, competence requirements stipulated in the PGD must be adhered to.

4.3. Continuing education and training

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

5. Audit trail

Record the following information:

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

Records should be kept in line with local procedures.

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

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

6. Additional references

Practitioners operating the PGD must be familiar with:

- **Immunisation against Infectious Disease [Green Book]**
- **Immunisation against Infectious Disease [Green Book] COVID-19 chapter**
- **Bimervax® Manufacturer's product information/ Summary of Product Characteristics**
- **Educational resources for registered professionals produced by Public Services Delivery Scotland.**
- All relevant JCVI **statements**.
- All relevant Scottish Government advice including the **relevant CMO letter(s)**
- **Revaccination of patients following haematopoietic stem cell transplant or CAR-T treatment schedule**
- **Prescribing and dispensing / supply / administration by the same healthcare professional - Royal College of Pharmacy.**
- **Professional guidance to support prescribing and dispensing / supply / administration by the same healthcare professional - Royal College of Pharmacy.**
- **Scottish Government Section 47 certificate of incapacity**
- **PSDS adults with incapacity**
- **COVID-19 vaccination programme: information for healthcare practitioners - GOV.UK**

7. PGD for administration of Bimervax® LP.8.1 (COVID-19 vaccine [recombinant, adjuvanted]) PGD V1.0 (valid from 24 September 2026 and expires 30 April 2027): 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 Bimervax® LP.8.1 (COVID-19 Vaccine (recombinant, adjuvanted)) vaccine 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 **NHS Greater Glasgow and Clyde** for the above-named healthcare professionals who have signed the PGD to work under it.

Lead clinician for the service area:

Name …….

Signature ……..

Date ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

8. Version history

Version	Date	Summary of changes
1.0	24 September 2026	New PGD template to support delivery of the Autumn 2026 COVID-19 vaccination programme to eligible individuals aged 12 years and over. This template replaces the previous Nuvaxovid JN.1 V3.1 PGD template.