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Public Health Scotland

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

Publication date: 30 September 2026

Valid From: 30 September 2026

Expiry: 30 April 2027

Version 1.0



Translations and other formats are available on request at:

phs.otherformats@phs.scot

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VGD

Most recent changes

Version	Date	Summary of changes
1.0	30 September 2026	New VGD to support delivery of the Autumn 2026 COVID-19 vaccination programme to eligible individuals aged 12 years and over.

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VGD

1. About the Vaccine Group Direction (VGD)

This VGD is for the administration of Bimervax® LP.8.1 (COVID-19 vaccine [recombinant, adjuvanted]) vaccine accordance with the national COVID-19 vaccination programme.

This VGD is for the administration of Bimervax® LP.8.1 vaccine by appropriately trained persons in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**.

Public Health Scotland, in the capacity of the Scottish public health agency, has produced and authored this VGD, for the purpose of providing protection against an infectious disease, namely COVID-19, as part of a vaccination programme which has been approved by Scottish Ministers.

In accordance with regulation 235A, this VGD must be authorised by/on behalf of a senior manager of an NHS Board prior to use in said NHS Board and be in effect at the time at which the medicinal product is administered.

This VGD will facilitate the delivery of the national COVID-19 Vaccination Programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as “the provider”. Please note that in the context of this VGD, “the provider” means:

a. a Health Board,
b. a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
c. an organisation delivering services on behalf of a Health Board.

This VGD may be followed wholly from assessment of an individual through to post-vaccination by a single appropriately specified registered healthcare professional able to operate under Patient Group Directions, as specified in the relevant parts of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**. **Please note that nursing associates and operating department practitioners are not enabled to consent individuals under VGDs but may carry out**

non-registrant tasks provided they are supervised by a registered healthcare professional able to operate under Patient Group Directions. Alternatively, obtaining consent from, and assessment of, an individual may be undertaken by a registered healthcare professional with the processes of vaccine preparation, administration and recording undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision by a registered healthcare professional.

Where multiple person delivery models are used the provider must ensure that all elements of the VGD are complied with in the provision of the vaccination to each individual. **Please note that only the individual administering a vaccine may undertake reconstitution or dilution and stages 2 and 3 (preparation and administration) must be undertaken by the same individual. Vaccine preparation and administration cannot be separated.**

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this VGD. As a minimum, competence requirements stipulated in the VGD under 'Characteristics of staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the VGD at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the VGD.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

The clinical supervisor must be identifiable to individuals receiving vaccination. Whenever the VGD is used, the name of the clinical supervisor taking responsibility and all of the persons working under different activity stages of the VGD must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the VGD must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the VGD as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the VGD in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this VGD. Persons working in accordance with this VGD must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this VGD or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this VGD. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that any organisation they make arrangements with to deliver services on their behalf adheres to this VGD. The final authorised copy of this VGD should be kept by Health Boards for 8 years after the VGD expires. Providers adopting authorised versions of this VGD should also retain copies, along with the details of those authorised to work under it, for 8 years after the VGD expires.

Any provider administering Bimervax® LP.8.1 (COVID-19 vaccine [recombinant, adjuvanted]) vaccine under VGD must work strictly within the terms of this VGD. **Authorising organisations must not alter, amend or add to the clinical content of this document; such action will invalidate the clinical sign-off with which it is provided in accordance with the regulations. The legal validity of this VGD is contingent on those authorising section 2 and Annex B complying with the above.**

The national COVID-19 vaccination programme may also be provided under patient group direction, or on a patient specific basis, by or on the directions of an appropriate prescriber. Administration in these instances is not related to this VGD.

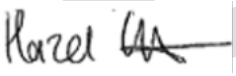
Providers must check that they are using the current version of this VGD. Amendments may become necessary prior to the published expiry date. Current versions of VGDs authored by Public Health Scotland in accordance with regulation 235A of the Human Medicines Regulation 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**, can be requested by emailing phs.vaccination@phs.scot Any concerns regarding the content of this VGD should also be sent to this email address.

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2. Approval and Clinical Authorisation

This VGD is not legally valid, in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**, until authored by Public Health Scotland and authorised by NHS Boards in Scotland.

On 29 September 2026, Public Health Scotland approved and authored this VGD in accordance with regulation 235A of the Human Medicines Regulations 2012, as amended by **the Human Medicines (Amendment) Regulations 2026**. Approval of clinical information in Annex A is via the Clinical Governance and Oversight Group of the Scottish Vaccination and Immunisation Programme on behalf of Public Health Scotland for the delivery of the national COVID-19 Vaccination Programme, with defined limitations to authorisation that may be updated from time to time as may be required.

Clinical author signatories – Public Health Scotland			
Role	**Name**	**Signature**	**Date**
Medical	Sam Ghebrehewet		29 September 2026
Pharmacy	Hazel Close		29 September 2026
Nursing	Jill Madden		29 September 2026

Authorised for use by the following organisations and/or services
<Insert NHS Board or commissioned service details here>
Limitations to authorisation
This authorisation applies to the administration of Bimervax® LP.8.1 vaccine, only under the conditions set out in the authorisation license set out by the Medicines and Healthcare products Regulatory Agency.

Clinical authorisation acting as a senior manager for/on behalf of the NHS Board or commissioned service			
Role	**Name**	**Sign**	**Date**
Medical			
Pharmacy			
Nursing			
Other (for Local addition as appropriate)			

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3. Characteristics of staff

1. Characteristics of staff

The provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this VGD. In doing so the provider must establish that those persons:

a) demonstrate appropriate knowledge and skills to work under the Vaccine Group Direction for the administration of Bimervax® LP.8.1 vaccine.

b) have met the requirements of the relevant Public Service Delivery (PSD) Scotland, Vaccination Proficiency document as appropriate at https://learn.nes.nhs.scot/82079

Classes of persons permitted to administer medicinal products under this VGD		
This VGD may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this VGD under the supervision of the appropriately specified registered healthcare professional[1]. Activity stages of the vaccination pathway under this VGD:		
Stage 1	a) Assessment of the individual presenting for vaccination b) Provide information and obtain informed consent c) Provide advice to the individual, including written information.	Registered Healthcare Professionals Only

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Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff
Stage 4	Record keeping	Registered Healthcare Professionals, non- registered professionals or non-registered Armed Forces staff

***From 1 April 2026, only the person administering a vaccine may carry out reconstitution or dilution. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**

Providers are responsible for assessing the competency of, designating and recording the names of, all those persons permitted to administer under this VGD.

[1]The following specified registered healthcare professionals are permitted to operate under the VGD stages 1 to 4, subject to the requirements set out below:

- 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 currently registered with the General Dental Council.
- Optometrists currently registered with the General Optical Council.

The following professionals (who are in the main non-registered) are permitted to administer under the VGD, with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers
- Pre-registration pharmacists and other pharmacy support practitioners
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists,orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered
- Healthcare Scientists
- Dental nurses
- Physician's assistants
- Nursing associates
- Operating department practitioners
- Scottish Ambulance Service Ambulance Technicians

The following non-registered Armed Forces staff are permitted to administer under the VGD with appropriate supervision as set out below, subject to the requirements set out

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below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements

All those working under this VGD must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person delivery models are used, the provider must ensure that all elements of the VGD are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this VGD. As a minimum, competence requirements stipulated in the VGD must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this VGD before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the COVID-19 vaccination programme in that locality. VGDs do not remove inherent obligations or accountability.

All practitioners operating under this VGD must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this VGD must adhere.

Training

- They must have undertaken training appropriate to this VGD and relevant to their role, as required by local policy and health board standard operating procedures

and in line with the training recommendations for persons vaccinating for COVID-19.

- They must have met the requirements set out in the relevant Public Service Delivery (PSD) Scotland Vaccination Proficiency document.

Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications / exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated. All persons must be one of above noted registered professionals.
- Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant Public Service Delivery (PSD) Scotland Vaccination Proficiency document. They should be observed preparing and administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to prepare and administer vaccines safely and competently.
- Experienced persons should use the relevant PSD Scotland Vaccination Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer Bimervax® LP.8.1 vaccine. They must have completed local Infection Prevention and Control (IPC) training and comply with the vaccination guidance.

In addition and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SmPC) and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of **The Green Book Chapter.**
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the

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national COVID-19 Vaccination Programme.

- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed applicable basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's VGDs and relevant COVID-19 Vaccination Programme online resources.
- For those preparing and administering the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for preparing the correct dose.
- For those preparing and administering the vaccine, they must be competent in the intramuscular injection technique, this should include a practical element.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management app.
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

Supervision

- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential.
- Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 Vaccination Programme.
- Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the VGD and provide clinical supervision for the overall provision of clinical care provided under the VGD.

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4. Annex A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the Vaccine Group Direction

4.1 Clinical condition or situation to which this Vaccine Group Direction applies

Category	Description
Inclusion Criteria	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. The eligible groups are the following: 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. • 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.
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

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	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.
Cautions/ needfor 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.

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	In 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

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	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 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

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	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.
Action if excluded	Specialist advice must be sought on the vaccine and circumstances under which it could be given as immunisation using a patient specific direction may be indicated. The risk to the individual not being immunised must be taken into account. Document the reason for exclusion and any action taken in

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	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.
Action if person declines	Advise the individual 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.

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4.2 Description of treatment

Category	Description
Name of medicine	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.
Form	Emulsion for injection
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.

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	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.
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.
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 VGD.

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	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 VGD. **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.**
Duration of treatment	See frequency section.
Maximum or minimum treatment period	See frequency section.
Quantity to administer	See frequency section.
▼ 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**.

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Legal category	Prescription Only Medicine (POM)
Is the use outwith the SPC?	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

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	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 VGD.
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.
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.

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4.3 Adverse reactions

<table>
<tr><th>Category</th><th>Description</th></tr>
<tr><td>Warnings including possible adverse reactions</td><td>
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
<table>
<tr><th>Vaccine</th><th>Very Common</th><th>Common</th></tr>
<tr><td>Bimervax® LP.8.1</td><td>headache, myalgia, injection site pain, fatigue</td><td>lymphadenopathy, diarrhoea, vomiting, nausea, injection site swelling, erythema and induration, pyrexia, axillary pain</td></tr>
</table>
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.
</td></tr>
</table>

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	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**.
Management of adverse reactions	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'.
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 Yellow Card reporting scheme on **http://www.mhra.gov.uk/yellowcard**

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	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. 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 carerincluding 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: o chest pain o shortness of breath o feelings of having a fast-beating, fluttering, or pounding heart • As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **https://yellowcard.mhra.gov.uk/** • As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be

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	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.
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.
Follow up	As above.

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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 professional overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis.

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5. Audit Trail/Records

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 • 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 vaccine group direction. Records should be kept 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.

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6. References

Name	Description
Additional references	• 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

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	• **COVID-19 vaccination programme: information for healthcare practitioners - GOV.UK**

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7. Annex B: Practitioner authorisation sheet

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

Valid from:

Expiry:

Before signing this VGD, check that the document has had the necessary authorisations. Without these, this VGD is not lawfully valid.

Practitioner

By signing this VGD you are indicating that you agree to its contents and that **you will work within it.**

VGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each practitioner to practice only within the bounds of their own competence and any appropriate professional code of conduct.

I confirm that I have read and understood the content of this VGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

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Person authorising on behalf of the Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this VGD. I give authorisation on behalf of (**insert name of organisation)** for the above named health care professionals who have signed the VGD to work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this VGD.

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8. Annex C: Clinical Supervision sheet

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

Valid from:

Expiry:

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the VGD.

Activity stages of the vaccination pathway under this VGD:

Stage 1	a) Assessment of the individual presenting for vaccination b) Provide information and obtain informed consent c) Provide advice to the individual, including written information	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation **Delegation of this stage must be to the same practitioner as stage 3*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	Vaccine Administration **Delegation of this stage must be to the same practitioner as stage 2*. Vaccine preparation and administration cannot be separated.**	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

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Stage 4	Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

***From 1 April 2026, only the person administering a vaccine may carry out reconstitution or dilution. Therefore, vaccine preparation and administration must be completed by the same practitioner, where these steps have been delegated by the practitioner working under stage 1.**

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the VGD. Persons working under the VGD may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this VGD, check that the document has had the necessary authorisations. Without these, this VGD is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

VGD

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date	Clinical Supervisor Initials

Note to Clinical Supervisor

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation. This authorisation sheet should be retained to serve as a record of clinical supervision arrangements for those working under this VGD.

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9. Version history

Version	Date	Summary of changes
1.0	30 September 2026	New VGD to support delivery of the Autumn 2026 COVID-19 vaccination programme to eligible individuals aged 12 years and over.

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