NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Hepatitis B Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from Public Health Scotland Administration of Hepatitis B vaccine for Travel Indications Patient Group Direction (PGD) Template, Version 2.1 – PHS Publication date 22nd July 2024		**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/Travel_HepB/1461	**Review Date:** 28th February 2026 **Expiry Date:** 28th February 2026	**Date Approved by NoS:** 31st October 2024

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 2.1

Revision History for NoS:

NoS PGD that has been superseded	NoS/PGD/Travel_HepB/MGPG1258, Version 1

Most recent changes NoS

Version	Date of change	Summary of Changes	Section heading
2	5th March 2024 (PHS Version Unpublished by NoS)		
2.1	06 August 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

PHS recent changes

Version	Date	Summary of changes
2.0	1 February 2024	• This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • Is the use out with the SmPC section updated to remove reference to use of adult strength formulations for paediatric patients as there is no current shortage of paediatric formulations. • Additional information section updated to include sexual health advice. Observation following vaccination section updated to include advice on driving post-immunisation.
2.1	22 July 2024	The following changes to version 2.0 of the PGD have been made: • Exclusion criteria to reflect Green Book wording on previous infection. • Section 2.1 name of product updated with additional brands. • Dosage and Frequency sections updated to reference relevant tables in Chapter 18. • Section 2.8 updated with additional brands. • Section 2.10 updated with additional brands. • Section 3.1 updated to align with Green Book chapter wording.

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

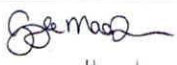
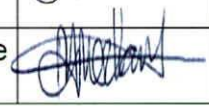
This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland and adapted by North of Scotland PGD Group (NoS) to assist NHS Boards. NHS Boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer vaccine 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.

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	Daniel Chandler	Signature		Date Signed	30/09/2024
Pharmacist	Gayle MacDonald	Signature		Date Signed	08/10/2024
Nurse	Pauline Merchant	Signature		Date Signed	17/10/2024

Approved for use within NoS by:

NoS Group Chair	Signature	Date Signed
Lesley Coyle		23/10/2024

Authorised and executively signed for use within NoS by:

NHS Grampian Chief Executive	Signature	Date Signed
Adam Coldwells – Interim Chief Executive		31/10/2024

Version 2.1 – Approved for NoS from 31st October 2024

1. Clinical situation

1.1. Indication

Active immunisation of individuals who are deemed to be at risk from exposure to hepatitis B virus.

1.2. Inclusion criteria

Individuals who:

- Intend to travel to or reside in countries where hepatitis B vaccination is currently recommended for travel in accordance with national recommendations issued by TRAVAX https://www.travax.nhs.uk/
- The risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history.

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 any hepatitis B containing vaccine or to any components of the vaccines (refer to relevant SmPC)
- are solely at occupational risk of hepatitis B exposure
- are known to be HBsAg, anti-HBs or anti-HBc positive
- are requiring Post Exposure Prophylaxis. Seek specialist advice.
- are known to be on haemodialysis, renal transplantation programmes or have chronic renal failure. Seek specialist advice.
- are HIV positive. Seek specialist advice.
- have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free
- are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation).

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

The Green Book advises there are very few individuals who cannot receive hepatitis B containing vaccines.

When there is doubt, appropriate advice should be sought from the immunisation co-ordinator or health protection team rather than withholding the vaccine.

The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear.

Co-administration of other vaccines

Hepatitis B vaccines can be given at the same time as other vaccines, including other travel vaccines. 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 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 evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated vaccines. Since hepatitis B vaccine is an inactivated vaccine, the risks to the foetus are negligible and it should be given where there is a definite risk of infection.

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.

Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).

Individuals who are solely at occupational risk of B exposure should be referred to their employer's occupational health provider for vaccination.

Individuals known to be HBsAg, anti-HBs or anti-HBc positive should be advised that vaccination is not necessary. However, immunisation should not be delayed while awaiting any test results.

Temporary exclusion

In case of postponement due to acute severe febrile illness, arrange a future date for immunisation.

1.6. Action if patient 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.

Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).

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

Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) (HepB):

- **Engerix B®** 10micrograms/0.5mL suspension for injection in prefilled syringe
- **Engerix B®** 20micrograms/1mL suspension for injection in prefilled syringe
- **HBvaxPRO Paediatric®** 5micrograms/0.5mL suspension for injection in prefilled syringe
- **HBvaxPRO®** 10micrograms/1mL suspension for injection in prefilled syringe
- **PreHevbri®** 10micrograms/1mL suspension for injection in a vial
- **HEPLISAV B®** 20micrograms/0.5mL solution for injection in a pre-filled syringe

2.2. Route of administration

Hepatitis B-containing vaccines are routinely given intramuscularly in the upper arm or anterolateral thigh.

For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given in accordance with the recommendations in the Green Book Chapter 4.

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

Dependent on product, see Table 18.2 Dosage of monovalent hepatitis B containing vaccines by age in Green Book Chapter 18.

2.4. Frequency

Refer to Table 18.5: Hepatitis B immunisation schedules in Chapter 18 and relevant indication sections for the recommended schedule(s).

It is important immunisations are provided on time, as delay will increase the chance of infection being acquired.

Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be resumed and completed.

Individuals who require other vaccines at the same time as a scheduled hepatitis B dose may receive these as separate vaccine products or the scheduled hepatitis B dose may be fulfilled by the administration of a multivalent vaccine, such as HepA/HepB combined vaccine.

Reinforcing Doses

The current UK recommendation for travel purposes is that immunocompetent children and adults, who have received a complete primary course of immunisation (see schedule above), do not require a reinforcing dose of a hepatitis B containing vaccine.

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, PreHevbri® and HEPLISAV B®. The Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for newly approved vaccines. All suspected adverse drug reactions should be reported using the MHRA Yellow Card Scheme.

2.9. Legal category

Prescription only medicine (POM).

2.10. Is the use outwith the SmPC?

As there is little or no data pertaining to use of either PreHevbri® or HEPLISAV B® in the paediatric population, neither of these vaccines should be given to individuals under 18 years. Whilst it is preferable that the same vaccine brand is used throughout the course, PreHevbri® or HEPLISAV B® may be given if the brand used for the first dose is not available, to avoid a delay in protection.

Engerix B® very rapid schedule (given at 0, 7 and 21 days) is licensed for those from 18 years of age but may be used off-label in those from 16 to 18 years of age where it is important to provide rapid protection and to maximise compliance in accordance with Chapter 18 of the Green Book.

Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Vaccine should be stored according to the conditions detailed 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 or national vaccine incident guidance.

Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.

2.11. Storage requirements

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

Store in the original packaging to protect from light.

Do not freeze.

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 off-label use or appropriate disposal.

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.

Immunological response may be diminished in those receiving immunosuppressive treatment.

Sexual contacts of individuals infected with hepatitis B should be advised regarding the appropriate use of condoms; a reasonable level of protection can be assumed following the second dose, provided completion of the schedule can be assured.

Because of the long incubation period of hepatitis B, it is possible forunrecognised infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases.

The vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis A, hepatitis C and hepatitis E viruses.

3. Adverse reactions

3.1. Warnings including possible adverse reactions and management of these

For full details/information on possible side effects, refer to the marketing authorisation holder's SmPC.

Hepatitis B vaccine is generally well tolerated and the most common adverse reactions are soreness and redness at the injection site. Other reactions that have been reported but may not be causally related include fever, rash, malaise and an influenza-like syndrome, arthritis, arthralgia, myalgia and abnormal liver function tests. Headache is a very common reaction to both PreHevbri® and HEPLISAV B® vaccine.

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

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

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.

3.3. Advice to patient or carer including written information

Written information to be given to individuals:

- Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.
- Supply immunisation promotional material as appropriate.

Individual advice / follow up treatment:

- Inform the individual/carer of possible side effects and their management
- 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.
- When applicable, advise individual/parent/carer when the subsequent dose is due.
- Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).
- Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation.

3.4. Observation following vaccination

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

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.

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 persons operating this PGD:

- demonstrate appropriate knowledge and skills to work under 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.
- 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.

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 - Chapter 18 - Hepatitis B
- Current edition of British National Formulary.
- Marketing authorisation holders Summary of Product Characteristics.
- Professional Guidance on the Administration of Medicines in Healthcare settings 2019.
- Professional Guidance on the Safe and Secure Handling of Medicines

7. Version history

Version	Date	Summary of changes
1.0	1 February 2022	• New PGD
2.0	1 February 2024	• This PGD has undergone minor rewording, layout, formatting changes for clarity and consistency with other PHS national specimen PGDs. • Is the use out with the SmPC section updated to remove reference to use of adult strength formulations for paediatric patients as there is no current shortage of paediatric formulations. • Additional information section updated to include sexual health advice. • Observation following vaccination section updated to include advice on driving post-immunisation.
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2.0	5th March 2024 (PHS Version Unpublished)	Reference to NoS Appendix 1 and 2.	Authorisation
		Training requirements for NoS.	Continuing education and training
2.1	06 August 2024	Reference to NoS Appendix 1 and 2	Authorisation
		Training requirements for NoS	Continuing education and training

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

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

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

Patient Group Direction For The Administration Of Hepatitis B Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1

I have completed the appropriate training to my professional standards enabling me to administer 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: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

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 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 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 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 Hepatitis B Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Hepatitis B Vaccine For Travel Indications By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles, Version 2.1					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**