# Patient Group Direction (PGD)

## Administration of hepatitis B vaccine for travel indications

Publication date: 01 February 2022

**<u>NOT FOR USE</u> IN RENAL PATIENTS ON HAEMODIALYSIS, A RENAL TRANSPLANTATION PROGRAMME OR HAVE CHRONIC RENAL FAILURE (CKD STAGE 4 OR 5) THAT IS LIKELY TO REQUIRE HAEMODIALYSIS OR TRANSPLANT PLEASE USE PH38 PGD - Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) v1 Feb2022 FOR THIS PATIENT GROUP**

**Version 1.0**
**Effective from: 01 February 2022**
**Review date: 31 January 2024**

## Version history

| Version | Date | Summary of changes |
|---|---|---|
| 1.0 | 01/02/22 | Version 1.0 new PGD |

# Contents

# Authorisation

## PGD hepatitis B vaccine for travel indications

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

The qualified health professionals who may administer hepatitis B 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 (SPC) 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 Borders by:**

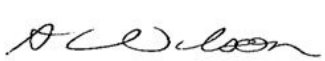
**Doctor** ….Dr Tim Patterson…….... **Signature** 

**Pharmacist** ….Adrian Mackenzie…… **Signature** 

**Nurse** ……Jill Madden…… **Signature** 

**Approved on behalf of NHS Borders by:**

**Medical Director** ……Dr Lynn McCallum…… **Signature** 

**Director of Pharmacy/**
**Senior Pharmacist** ……Alison Wilson…… **Signature** 

**Clinical Governance Lead** …Sarah Horan…… **Signature** 

**Date approved: 21/02/2022**

**Effective from:** 01/02/2022 **Review date:** 31/01/2024

# Clinical situation

| Category | Description |
|---|---|
| **Indication** | For active immunisation of individuals who are deemed to be at risk from hepatitis B Virus. |
| **Inclusion criteria** | • Valid consent has been given to receive the vaccine.<br>Individuals who:<br>• 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 **www.travax.nhs.uk/destinations/**<br>the risk of exposure should be determined after careful risk assessment of an individual's itinerary, duration of stay, planned activities and medical history. |
| **Exclusion criteria** | Individuals who:<br>• 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 SPC)<br>• are solely at occupational risk of hepatitis B exposure<br>• previous confirmed hepatitis B infection<br>• are requiring Post Exposure Prophylaxis. Seek specialist advice.<br>• are on haemodialysis, renal transplantation programmes or have chronic renal failure. Seek specialist advice.<br>• are HIV positive. Seek specialist advice.<br>• have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free<br>• are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) |
| **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 lead clinician rather than withholding the vaccine.<br>Individuals who are immunosuppressed may not make a full antibody response. This should be discussed with the appropriate/relevant specialist.<br>Individuals who are solely at occupational risk of B exposure should be referred to their employer's occupational health provider for vaccination.<br>The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, |

| Category | Description |
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| | 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.<br><br>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. |
| **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 of not being immunised must be taken into account.<br><br>Document the reason for exclusion and any action taken in accordance with local procedures. Inform or refer to the lead clinician.<br><br>Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).<br><br>Individuals who are solely at occupational risk of hepatitis B exposure should be referred to their employer's occupation health provider for vaccination.<br><br>In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged.<br><br>Individuals who have had a confirmed anaphylactic reaction to a previous dose of a hepatitis B containing vaccine or any components of the vaccines should be referred to a clinician for specialist advice and appropriate management. |
| **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.<br><br>Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).<br><br>Document advice given and decision reached. Inform or refer to the lead clinician in charge. |

# Description of treatment

<table>
<tr><th>Category</th><th>Description</th></tr>
<tr><td>Name of medicine/Form/strength</td><td>Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) (HepB)<br>• Engerix B® 10micrograms/0.5ml suspension for injection in prefilled syringe<br>• Engerix B® 20micrograms/1ml suspension for injection in prefilled syringe<br>• HBvaxPRO® 5micrograms/0.5ml suspension for injection in prefilled syringe<br>• HBvaxPRO® 10micrograms/1ml suspension for injection in prefilled syringe</td></tr>
<tr><td>Route of administration</td><td>Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm or the anterolateral area of the thigh muscle in small children.<br><br>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 .<br><br>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.</td></tr>
<tr><td>Dosage</td><td><u>0 - 15 years:</u><br>Engerix B®* 0.5ml (10 micrograms)<br>HBvaxPRO® 0.5ml (5 micrograms)<br><br><u>>16 years:</u><br>Engerix B® 1ml (20* micrograms)<br>HBvaxPRO® 1ml (10 micrograms)<br><br>*1ml (20µg) of Engerix B may be given to children 11–15 years of age if using the two-dose schedule (see below)</td></tr>
<tr><td>Frequency</td><td>
<table>
<tr><th>Schedule</th><th>Examples of when to use this schedule</th></tr>
<tr><td>Usual pre exposure prophylaxis accelerated schedule:<br>• 3 doses at 0, 1, and 2 months<br>• A fourth dose given 12 months after the first dose for individuals at continued high risk</td><td>Used for individuals of all ages for pre-exposure prophylaxis.</td></tr>
<tr><td>Alternative schedule:<br>• 3 doses at 0, 1, and 6</td><td>This is rarely the most appropriate schedule. It should only be used when rapid protection is not required and there is a high likelihood of compliance</td></tr>
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<table>
<tr><th>Category</th><th>Description</th></tr>
<tr><td></td><td>
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<tr><td>months</td><td>with the regimen.</td></tr>
<tr><td>Two dose schedule of Engerix B® only:<br>• 2 doses of adult strength (20 microgram) vaccine at 0 and 6 months</td><td>Only to be used for individuals 11 to 15 years of age, when there is a low risk of hepatitis B infection during the course and completion of the course can be assured.</td></tr>
<tr><td>Very rapid (super accelerated) schedule of Engerix B® only:<br>• 3 doses at 0, 7 days and 21 days<br>• further dose 12 months after the first dose is recommended to be considered protected</td><td>To be used for individuals from 16 years of age (see Off-label use) who are at immediate risk and when very rapid immunisation is required.</td></tr>
<tr><td></td><td></td></tr>
</table>
HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.<br><br>Note: Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate. This PGD does not cover the administration of multivalent vaccines.<br><br><u>Reinforcing Doses</u><br><br>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.</td></tr>
<tr><td>Duration of treatment</td><td>As above</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>As above</td></tr>
<tr><td>Quantity to supply/administer</td><td>One dose per occasion</td></tr>
<tr><td>▼ black triangle medicines</td><td>No</td></tr>
<tr><td>Legal category</td><td>Prescription Only Medicine (POM)</td></tr>
<tr><td>Is the use out with</td><td>Engerix B® very rapid (super accelerated) schedule (given at 0, 7 and 21 days)</td></tr>
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| Category | Description |
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| **the SPC?** | is licensed for those from 18 years of age but may be used off-label in those 16 and 17 years of age where it is important to provide rapid protection and to maximise compliance in accordance with Chapter 18 of 'The Green Book'.<br><br>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.<br><br>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. |
| **Storage requirements** | Vaccine should be stored at a temperature of +2° to +8°C.<br><br>Store in the original packaging to protect from light.<br><br>Do not freeze.<br><br>NHS board guidance on Storage and Handling of vaccines should be observed.<br><br>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. |
| **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.<br><br>Immunological response may be diminished in those receiving immunosuppressive treatment.<br><br>Because of the long incubation period of hepatitis B, it is possible for unrecognised infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases.<br><br>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.<br><br>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. |

| Category | Description |
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| | 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. |

## Adverse reactions

| Category | Description |
|---|---|
| **Warnings including possible adverse reactions and management of these** | For full details/information on possible side effects, refer to the marketing authorisation holder's SPC.<br><br>Local reactions following vaccination are very common such as pain, swelling or redness at the injection site, induration.<br><br>Low grade fever, fatigue, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after hepatitis B vaccination.<br><br>As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available.<br><br>In the event of severe adverse reaction individual should be advised to seek medical advice. |
| **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://yellowcard.mhra.gov.uk/**<br><br>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. |
| **Advice to patient or carer including written information** | Written information to be given to individuals:<br>• Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine.<br><br>Individual advice / follow up treatment:<br>• Inform the individual/carer of possible side effects and their management.<br>• The individual should be advised to seek medical advice in the event of a |

| Category | Description |
|---|---|
| | severe adverse reaction.<br>• Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk/<br>• When applicable, advise individual/parent/carer when the subsequent dose is due.<br>• Advise individuals of preventative measures to reduce exposure to hepatitis B (such as avoiding exposure to blood and bodily fluids).<br>• Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation. |
| **Observation following vaccination** | Following immunisation, patients remain under observation in line with NHS board policy. |
| **Follow up** | As above |
| **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. |

## Characteristics of staff authorised under the PGD

| Category | Description |
|---|---|
| **Professional qualifications** | The following classes of registered healthcare practitioners are permitted to administer vaccines:<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC)<br>• 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)<br>• dental hygienists and dental therapists registered with the General Dental |

| Category | Description |
|---|---|
| | Council<br>• optometrists registered with the General Optical Council. |
| **Specialist competencies or qualifications** | Persons must only work under this PGD where they are competent to do so.<br>All persons operating this PGD:<br>• must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it<br>• must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information,<br>• must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent<br>• must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine<br>• must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br>Employer:<br>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<br>As a minimum, competence requirements stipulated in the PGD must be adhered to. |
| **Continuing education and training** | All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD. |

## Audit trail

| Name | Description |
|---|---|
| **Record/ audit trail** | Record:<br>• that valid informed consent was given<br>• name of individual, address, date of birth and GP with whom the individual is registered<br>• name of person that undertook assessment of individual's clinical suitability for vaccine<br>• name of person that administered the vaccine<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine<br>• batch number<br>• where possible expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if excluded or declines immunisation<br>• details of any adverse drug reactions and actions taken<br>• administered under PGD<br>Records should be kept in line with local procedures.<br>Local policy should be followed to encourage information sharing with the individual's General Practice.<br>All records should be clear, legible and contemporaneous and in an easily retrievable format. |

# Additional references

| Name | Description |
|---|---|
| **Additional references** | Immunisation against Infectious Disease [Green Book]<br>**https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book**<br><br>Immunisation against Infectious Disease [Green Book] chapters 18<br>**https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/628602/Greenbook_chapter__18.pdf**<br><br>Current edition of British National Formulary.<br><br>Marketing authorisation holder's Summary of Product Characteristics.<br><br>Professional Guidance on the Administration of Medicines in Healthcare Settings 2019<br>**https://www.rpharms.com/Portals/0/RPS document library/Open access/Professional standards/SSHM Admin/Admin Meds prof guidance.pdf/ver=2019-01-23-145026-567**<br><br>Professional Guidance on the Safe and Secure Handling of Medicines<br>**https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines**<br><br>PHE hepatitis B Vaccine Patient Group Direction (PGD) – V3<br><br>NHS GG&C hepatitis B vaccine PGD ref no: 2020/2065 |

# PGD for administration of hepatitis B vaccine for travel indications v1.0 Valid from: 01/02/2022 Expiry: 31/01/2024 - 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 the hepatitis B vaccine only in accordance with this PGD.

| Name of professional | Signature | Date |
|---|---|---|
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## 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 Borders** for the above named health care professionals who have signed the PGD to work under it.

Lead clinician for the service area

**Name** ……..

**Signature** ……..

**Date** ……

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.