Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Hepatitis B vaccine Renal Patient Group Direction (PGD)

for the administration of

Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)

by registered healthcare professionals

to

individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure that is likely to require haemodialysis or transplant

in Powys Teaching Health Board

Version number: PGD 0175 B

Reference Number: PGD 0175 B
Valid from: 17/03/2025
Review Date: 28/09/2027
Expiry Date: 28/02/2028

Change History		
Version number	**Change details**	**Date**
PGD 0175	Initial Issue PHE template adopted	21/05/2021
PGD 0175-A	Reviewed in line with UKHSA template v4.00 to: • include minor rewording of standard text, layout and formatting changes for clarity and consistency with organisation change, gateway requirements and other UKHSA PGDs • amend NHS England and NHS Improvement (NHSEI) to NHSE following completion of merger on 1 July 2022 • reformat Tables 1 and 2 and add a note regarding Engerix B® being supported for the indication and double dose by the SPC in dose and frequency section. • include facilities for management for anaphylaxis statement in cautions section for consistency • remove duplication of advising individuals of side effects in the patient advice section • update safeguarding details	30/04/2023

PGD 0175 B	Review issue in line with UKHSA Hep B Renal PGD template v5.00 to: • add pharmacy technicians, dieticians, podiatrists and occupational therapists in Section 1 and update qualifications and professional registration • update expert panel • include sensitivity to formaldehyde and potassium thiocyanate for HBVAXPRO®40 vaccine in criteria for exclusion • clarify the serological markers in exclusion criteria • include off-label use of HBVAXPRO®40 in 16 years and 17 years old and update dose and frequency section accordingly • provide clarity for the use of other Hep B brands for booster dose following primary immunisation with Fendrix® vaccine in off-label section • delete the note relating to use of double dose of Engerix B® 20micrograms not being supported by Green Book (GB) • state the doses to be supplied and administered with clarity for each vaccine in the quantity to be administered section • update disposal guidance • amend low fever to fever and add malaise to adverse reactions • clarify testing for evidence of infection and immunity in special considerations • include other factors that may reduce the immune response to hepatitis B vaccines in special considerations • update consent statement in records section • update references Reviewed to include minor rewording of standard text, layout and formatting changes for clarity and consistency with other UKHSA PGD templates and PTHB PGDs	17/03/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA template v5.0 developed by the following on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD Policy (also ratified by the UKHSA Medicines Governance Committee).

The UKHSA template has been adapted for use in PTHB.

Developed by the following health professionals on behalf of the UKHSA:

Developed By:	Name
Pharmacist (Lead Author)	Suki Hunjunt Lead Pharmacist Immunisation Programmes, UKHSA
Doctor	Sema Mandal Medical Consultant Epidemiologist & Deputy Director, Blood Safety, Hepatitis, STI and HIV Division, UKHSA
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation Programmes, UKHSA

Expert panel

Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Gayatri Amrithalingam	Consultant Epidemiologist, Immunisation Programmes, UKHSA
Jessica Baldasera	Health Protection Practitioner, North East Health Protection Team Regions Directorate, UKHSA
Alison Campbell	Screening and Immunisation Coordinator, Public Health Commissioning NHS England (NHSE) Midlands
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy NHS England
Rosie Furner	Advanced Specialist Pharmacist - Medicines Governance, Specialist Pharmacist Services (SPS)
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Shilan Ghafoor	Medicines Governance Lead Pharmacist, UKHSA
Greta Hayward	Consultant Midwife – Immunisation Programmes, UKHSA
Naveen Dosanjh	Senior Clinical Advisor - Medicines and Pharmacy Vaccinations Sub-Directorate - NHSE
Elizabeth Luckett	Senior Screening and Immunisation Manager, NHSE South West
Briony Mason	Vaccination Manager, Professional Midwifery Advocate, Vaccination and Screening, NHS England, West Midlands
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Lesley McFarlane	Lead Immunisation Nurse Specialist, Immunisation Programmes, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHSE London

PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	3/20/2025
Senior Pharmacist **Jayne Price**	Head of Community Services Medicines Management/ Pharmacy	DocuSigned by: Jayne Price A9AFDC3B15294CC...	3/20/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB Assistant Director of Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	3/25/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	3/20/2025

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD. Appendix A provides a staff accreditation sheet. Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)[1]. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2.**

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Enquiries relating to the content of this PGD, availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: Info.MedicinesManagement.Powys@wales.nhs.uk

[1] This includes any relevant amendments to legislation

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

1. Characteristics of staff

Qualifications and professional registration	All practitioners should only administer vaccination where it is within their clinical scope of practice to do so. Practitioners must also fulfil the additional requirements and continued training requirements to ensure their competency is up to date, as outlined in the section below. Registered professional with one of the following bodies: • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics, physiotherapists, dieticians, podiatrists, and occupational therapists currently registered with the Health and Care Professions Council (HCPC) The practitioners above must also fulfil the Additional requirements detailed below. Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Must have completed Patient Group Directions training (available via eLfH PGD eLearning programme. PTHB staff to access via ESR). Evidence of ongoing PGD training to be submitted to Line Manager annually– this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). Individuals operating under this PGD must be assessed as competent (see Appendix A)

	• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training and online training. Please contact PTHB Immunisation coordinator for further information • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain'. Completion of cold chain training (also available via ESR) • must be familiar with All Wales Advisory document on Ordering Storage and Handling of Vaccines • must be competent in the intramuscular and subcutaneous injection techniques • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date basic life support skills. • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Updating at least every 2 years on the administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed). Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD). Practitioners must make a self-declaration of competency on PADR (if relevant). The **personal**

	development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. Compliance with all mandatory NHS training (if relevant). Practitioners should be constantly alert to any subsequent recommendations from Welsh Government and/or Public Health Wales and/or NHS Wales and the UKHSA and other sources of medicines information. Note: The most current national recommendations should be followed but a Patient Specific Direction (PSD) may be required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD.**

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Indicated for the active immunisation of individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant in accordance with the recommendations given in Chapter 7 and Chapter 18 of Immunisation Against Infectious Disease: 'The Green Book'. **It is the responsibility of the administering healthcare professional to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the vaccination. If there is any reason for concern, seek medical advice.**
Criteria for inclusion	Individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant. • Consent given. Informed consent, from the

	individual or a person legally able to act on the individual's behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy • Medical and drug history taken, no reason for exclusion Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults, POVA) advice from the local Safeguarding team should be sought (see below).
Criteria for exclusion (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside the PGD's remit and another form of authorisation will be required)	Individuals for whom valid consent, or a 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of The Green Book). Individuals who: • are under 15 years of age • have had a confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine or to any components of the vaccine. HBVAXPRO®40 micrograms may contain traces of formaldehyde and potassium thiocyanate (see SPC) • are known to have positive serological markers, Hepatitis B surface antigen (HBsAg) and hepatitis B core IgM antibody (anti-HBc IgM) indicating current infection or positive Anti-HBcore (hepatitis B core antibody) as a marker of past hepatitis infection • do not have a renal indication for Hep B vaccination (see PGD0041 HepB vaccination) • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation) Refer to sections "Action to be taken if the individual is excluded" and "Action to be taken if the individual or carer declines treatment".
Cautions including any relevant action to be taken	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council UK.

	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. Use caution when vaccinating individuals with severe (such as anaphylactic) allergy to latex. The HBVAXPRO®40 vial stopper contains dry natural latex rubber; use an alternative vaccine if available. The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate. Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. (Refer to BNF/SPC for full list) Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub: • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk And • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 Advice can also be sought from local Safeguarding leads.
Action to be taken if the individual is excluded	Individuals who are under 15 years of age who are on haemodialysis, renal transplantation programmes or with chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant, should be

	referred for specialist advice on the appropriate vaccination schedule. A PSD is required as vaccination of these individuals is outside the remit of this PGD. Individuals who have had a confirmed anaphylactic reaction to a previous dose of Hep B vaccine or any components of the vaccine should be referred to a clinician for specialist advice and appropriate management. Individuals known to have markers of current (HBsAg) or past (anti-HBcore) hepatitis B infection should be advised that vaccination is not necessary. However, immunisation should not be delayed while awaiting any test results. Individuals who do not have a renal indication for Hep B vaccination should be managed in accordance with the HepB PGD0041. Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or PTHB Infection Control Team or the individual's clinician as required. Explain reason to individual / carer. The risk to the individual of not being immunised must be taken into account. Document the reason for exclusion and any action taken in the individual's clinical records. In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. For further information on consent see

	Chapter 2 of the 'Green Book'. The patient information leaflet should be available to inform consent. Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications. Document the advice given and the decision reached. In a GP practice setting, inform or refer to the GP as appropriate. Inform the Child Health department if appropriate – if any vaccination is declined for a child under 19 years, Child Health must be informed and appropriate form completed. Where appropriate, inform the GP using the local agreed system.
Arrangements for referral for medical advice	Refer to GP, specialist, or consultant in communicable disease control (CCDC) for clinical advice as necessary. Document any advice given.

3. Description of treatment

Name, strength and formulation of drug	Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)* (HepB) • Fendrix® 20 micrograms/0.5ml suspension for injection in pre-filled syringe***** • HBVAXPRO® 40micrograms/1ml suspension for injection in a vial • Engerix B® 20micrograms/1ml suspension for injection in pre-filled syringe *the hepatitis B surface antigen in Fendrix® is adjuvanted by AS04C For full formulations of each vaccine, see the respective SPCs. An appropriate vaccine product should be selected for the patient group to be treated see Dose and Frequency of Administration.
Legal category	Prescription Only Medicine (POM)
Black triangle▼	No

Off-label use	Administration of Fendrix® by deep subcutaneous injection to individuals with a bleeding disorder is off-label administration in line with advice in Chapter 4 and Chapter 18 of 'The Green Book'. Once the primary immunisation schedule has been started with Fendrix®, interchanging with other brands of Hep B vaccine is off-label, but permissible under this PGD. (Note: Following a completed primary schedule with Fendrix®, where a booster dose is required, any brand of Hep B vaccine can be used. See Dose and frequency below). The SPC for HBVAXPRO®40micrograms recommends use of the vaccine in adults. However, the vaccine can be used off-label to administer the vaccine to 16 to 17 years old (included) in accordance with the guidelines from the UK Kidney Association. Recommendations in 'The Green Book' Chapter 18 allow for concomitant administration of Hep B vaccine with other vaccines at a separate site when required. For Fendrix®, such administration would be off-label as, due to a lack of data, the SPC for Fendrix® advises an interval of 2 to 3 weeks be respected between the administration of Fendrix® and other vaccines. Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to the All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. 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.
Route and method of administration	Administer by intramuscular injection into the deltoid region of the upper arm (see 'The Green Book' Chapter 4). The buttock should not be used because vaccine efficacy may be reduced.

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.

For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see 'The Green Book' Chapter 4).

The vaccine may settle during storage, shake the vaccine well before administration to obtain a slightly opaque (HBVAXPRO®40) or turbid (Fendrix®/ Engerix B®), white suspension.

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.

The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk

Dose and frequency of administration

Current UK licensed Hep B vaccines contain different concentrations of antigen per millilitre.

Table 1: Current UK licensed Hep B vaccine doses for adolescents and adults with renal insufficiency including dialysis

Age	Vaccine	Dose	Volume
Individuals with renal insufficiency (dialysis and pre-dialysis patients) aged 15 years and over	Fendrix®	20 micrograms	0.5ml
16 years and over dialysis and pre-dialysis individuals	HBVAXPRO®	40 micrograms	1.0ml
Individuals with renal insufficiency and dialysis individuals aged 16 years and over	Engerix B®	2 x 20 micrograms	2 x 1.0ml

Table 2: Schedule for adolescents and adults with renal insufficiency including dialysis

Schedule	Examples of when to use this schedule
Fendrix®: • 4 doses at 0 then 1, 2 and 6 months after the first dose	Use for individuals from 15 years of age.
HBVAXPRO® 40micrograms / 1.0ml: • 3 doses at 0 then 1 and 6 months after the first dose	Use for individuals from 16 years of age.
Engerix B® 20micrograms / 1.0ml: • 4 double doses (2 x 20 micrograms) at 0 then 1, 2, 6 months after the first dose	Use for individuals from 16 years of age.
Booster (Fendrix 20 micrograms®, HBVAXPRO® 40micrograms / 1.0ml or Engerix B® 20micrograms / 1.0ml): • single dose administered if anti-HBs levels fall below 10mIU/ml in an individual who has previously responded to the vaccine (levels should be monitored annually) • single dose to haemodialysis patients travelling to highly endemic areas if they have not received a booster in the last 12 months	Individuals on haemodialysis: From 15 years of age Fendrix® From 16 years of age HBVAXPRO®40 or Engerix B®

Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be resumed but not repeated.
HBVAXPRO®40 and Engerix B® may be used interchangeably to complete the vaccine course. Once the primary immunisation schedule has been started with Fendrix®, interchanging with other brands of Hep B vaccine is off label (see Off-label section).

Administration of HBVAXPRO®40 in 16 years and 17 years old is off-label (see Off-label section).

Duration of treatment	Dependent on vaccine schedule, see Dose and frequency of administration.

<table>
<tr><td>Quantity to be administered</td><td>
<table>
<tr><th>Vaccine</th><th>Strength</th><th>Dose per administration</th></tr>
<tr><td>Fendrix®</td><td>20 micrograms</td><td>0.5ml</td></tr>
<tr><td>HBVAXPRO®</td><td>40 micrograms</td><td>1.0ml</td></tr>
<tr><td>Engerix B®</td><td>20 micrograms</td><td>2 x 1.0ml</td></tr>
</table>

see Dose and frequency of administration.
</td></tr>
<tr><td>Supplies</td><td>Supplies should be ordered directly from manufacturers/wholesalers.

Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see Protocol for ordering storage and handling of vaccines and ‘The Green Book’ Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.</td></tr>
<tr><td>Storage</td><td>Store at between +2°C to +8°C.

Store in original packaging in order to protect from light.

Do not freeze.

In the event of an unavoidable temperature excursion HBVAXPRO®40 can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours.

Stability data indicate Engerix B® is stable at temperatures up to 37°C for 3 days or up to 25°C for 7 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Protocols for the storage and handling of vaccines should be followed to prevent vaccine wastage.
See ‘MMP 427 Safe and Secure Management of Refrigerated Medicines and Vaccines SOP’ for details of actions required in the event of a fridge temperature excursion.</td></tr>
</table>

	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. Refer to Vaccine Incident Guidance and All Wales Advisory document on Ordering Storage and Handling of Vaccines. Any loss of vaccines due to expiry date or fridge failure/breaches in cold chain must be reported on ImmForm, to PTHB Immunisation co-ordinator (Powys.Immunisations@wales.nhs.uk), and via PTHB Datix reporting system Once for Wales Reporting System.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste (NHSE) and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. Hepatitis B-containing vaccines can be given at the same time as other vaccines (see Chapter 18). However, when other vaccines are given at the same time as Fendrix®, this is off-label (see Off-label section). A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site or induration.

	Fever, fatigue, malaise, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after Hep B vaccination. Hypersensitivity reactions and anaphylaxis can occur but are very rare. In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone. In case of anaphylaxis: - • Refer to adrenaline (epinephrine) PGD0017 and anaphylaxis procedure • Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E • Ensure reaction is fully documented in patient notes • Ensure all patient records are marked **ALLERGIC TO HEPATITIS B recombinant DNA (rDNA) vaccine (adsorbed). State the brand of vaccine administered.** • The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting system This list is not exhaustive. A detailed list of adverse reactions is available in the SPCs, which are available from the electronic Medicines Compendium website: www.medicines.org.uk Report any suspected adverse reactions to a doctor.
Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: Yellow Card | Making medicines and medical devices safer or search for MHRA Yellow Card in the Google Play or Apple App Store.

	Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales reporting system.
Written information to be given to individual or carer	Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Further information for printing and website links suitable for the public can be found on the Public Health Wales intranet site Public Health Wales Immunisation and Vaccine Preventable Disease Programme, NHS 111 Wales and Health Information Resources. For resources in accessible formats and alternative languages, please visit Home - Health Publications. Where applicable, inform the individual/parent/carer that the PIL with large print, Braille or audio CD can be ordered from the manufacturer (see electronic medicines compendium).
Patient advice and follow up treatment	Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek medical advice in the event of an adverse reaction. When administration is postponed advise the individual/parent/carer when to return for vaccination. The individuals / parent/carers should be informed about the importance of completing a course of hepatitis B immunisation.
Special considerations and additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a working telephone at the time of vaccination. **Limitations of Hep B vaccination** 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. 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. As with any vaccine, a protective immune response may not be elicited in all vaccines (see Chapter 18 for more detail). **Testing for evidence of infection or immunity** Individuals with kidney failure may have reduced response to the vaccine. Additional vaccine doses may need to be considered for individuals who do not respond or if after the primary vaccine series has been administered, the anti-HBs response is less than 10 IU/ml. See Table 2 Booster doses and refer to Chapter 18 for advice on response to vaccine and the use of additional doses. The role of immunological memory in individuals with chronic kidney failure on renal dialysis is not clear, and protection may persist only as long as anti-HBs levels remain above 10mIU/ml. Antibody levels should be monitored annually and if they fall below 10mIU/ml, a booster dose of vaccine should be given to people who have previously responded to the vaccine. (See Doses and Frequency and Chapter 18). It is recommended that recipients should be tested one to two months after the completion of the primary vaccine and non-responders managed based on the results as per Chapter 18. Other factors have been observed that reduce the immune response to hepatitis B vaccines such as, age over 40 years, obesity and smoking. (For further details see SPC and Chapter 18). **Choice of Hep B vaccine** The response to Hep B vaccine among individuals with renal failure is lower than among healthy adults. However, increased response rates have been reported in vaccines formulated for use in individuals with chronic renal failure. Therefore, the vaccines formulated for use in individuals with chronic renal

	insufficiency should be used for these individuals (see Chapter 18). **Pregnancy and breast-feeding** There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated vaccines. Since Hep B is an inactivated vaccine, the risks to the fetus are negligible and it should be given where there is a definite risk of infection (see Chapter 18).
Records	Record consultation details as required by local procedures. In addition, record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate • name of individual, address, date of birth and GP with whom the individual is registered • medical and drug history taken, including any allergies and previous adverse events • any reasons for exclusion or referral, including actions taken • printed name and signature of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and 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 via PGD, record PGD title and version number Records should be signed and dated (or a password controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed.

	If a vaccine is administered to a child up to 19 years of age, the local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement (based in Llandrindod Hospital for school age). A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	Hep B vaccine • Immunisation Against Infectious Disease: 'The Green Book' Chapter 4, last updated March 2013, Chapter 18, last updated August 2024 • Summary of Product Characteristic for Engerix B®, GlaxoSmithKline. 20 November 2024 Engerix B 20 micrograms/1 ml Suspension for injection in pre-filled syringe - Summary of Product Characteristics (SmPC) • Summary of Product Characteristic for HBVAXPRO®40micrograms. MSD Ltd. 15 December 2022 HBVAXPRO 40micrograms - Summary of Product Characteristics (SmPC) • Summary of Product Characteristic for Fendrix®. GlaxoSmithKline. 21 July 2023 Fendrix - Summary of Product Characteristics (SmPC) • Clinical Practice Guideline, Management of Blood Borne Viruses within the Haemodialysis Unit www.ukkidney.org/health-professionals/guidelines/guidelines-commentaries **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. NHSE NHS England » Health technical memoranda • National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018 https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • UKHSA Vaccine Incident Guidance Vaccine Incident guidance: responding to vaccine errors- GOV.UK

	• PHE Protocol for ordering storage and handling of vaccines. April 2014. www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines • All Wales Advisory document on Ordering Storage and Handling of Vaccines 7th Edition September 2017 • Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste. 2013. Available from: https://nwssp.nhs.wales/ourservices/specialist-estates-services/specialist-estates-services-documents/whtms-library/whtm-07-01-safe-management-of-healthcare-waste-pdf/

Appendix A – Staff Accredited to use the Patient Group Direction

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the PGD to work under it. *The authorising manager must use the competency checklist (below).*

Practitioner: By signing this PGD you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.

Printed name of health professional	Signature of health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be requested for audit purposes. This list should be kept by PTHB (or the provider organisation adopting an authorised version of the PGD) for 25 years after the PGD expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " comments	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number) _____			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.