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. Healthcare professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the administration of

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

by registered healthcare professionals

to

individuals considered at increased risk of exposure to hepatitis B virus,

at increased risk of complications of hepatitis B disease,

or post potential exposure to hepatitis B virus

in Powys Teaching Health Board

Version number: PGD0041 H

Reference Number: PGD0041 H
Valid from: 01/07/2025
Review Date: 31/10/2027
Expiry Date: 30/04/2028

Change History		
Version number	**Change details**	**Date**
PGD0041	Initial Issue	01/09/2009
PGD0041-A	Review issue and put in new PTHB template	01/12/2013
PGD0041-B	Review issue	18/11/2016
PGD0041-C	Review issue, use of new template	01/11/2020
PGD0041-D	PHE adoption • include chronic anaemia and those on remand in the inclusion criteria • include 'best-interests' decision in accordance with the Mental Capacity Act 2005, for consent • remove Engerix B® 20microgram/1ml suspension for injection vials, which have been discontinued • in dose and frequency section include post-exposure prophylaxis should be initiated rapidly. Babies born to hepatitis B infected mothers should receive the first dose of vaccine as soon as possible, ideally within 24 hours of birth. • reflect changes to 'The Green Book' recommendations for booster doses • include stability data for Engerix B® • in advice/ follow up section added the pre-school vaccinations visit provides an opportunity to check children on the selective neonatal hepatitis B immunisation pathway have been fully immunised against hepatitis B and tested for infection. • include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references	21/05/2021
PGD0041-E	PHE adoption: HepB PGD amended to: • removal of reference to booster doses for healthcare workers • include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs and updated references	10/11/2021

PGD0041 F	Review issue to adopt UKHSA template v5.00 to include: • individuals with incomplete primary vaccination against hepatitis B (since the change to the childhood immunisation programme in August 2017) • particulars pertaining to 2 additional licensed Hep B vaccines (PreHevbri® and HEPLISAV B®) • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGD templates • updated contact details for UKHSA Review issue to remove the exclusion for use in PTHB occupational health department for their own staff	01/11/2023
PGD 0041G	Review issue in line with UKHSA Notice of extension of the validity of the Hepatitis B (Hep B) vaccine PGD v5.0, pending anticipated revisions to the childhood immunisation programme and the impact of changes to the infant hexavalent regime on advice provided in the hepatitis B PGD. **UKHSA Publications gateway number: GOV-15399** Reviewed to: • remove the exclusion for use in PTHB occupational health department for their own staff • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs • add information regarding look-alike sound-alike vaccines	17/03/2025

PGD 0041H	Review issue in line with UKHSA PGD template v6.0 to include: • removal of the dose of hepatitis B at 12 months of age for infants on the selective neonatal hepatitis B pathway born on or after 1 July 2024, as detailed in Schedule 1 of Table 2. Advice to complete the Dried Blood Spot (DBS) at any time between 12 months and 18 months of age for children born on or after 1 July 2024, in line with updates to the routine childhood immunisation schedule • removal of PreHevbri® following its withdrawal from the UK market in 2024 • minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs and updated references • registered healthcare professionals named in both the Additional Roles Reimbursement Scheme (ARRS) and HMR2012 • advice on dosing strategies for people living with HIV Reviewed to: • remove the exclusion for use in PTHB occupational health department for their own staff • include minor rewording of standard text, layout and formatting changes for clarity and consistency with other PTHB PGDs • add information regarding look-alike sound-alike vaccines	01/07/2025

This Powys Teaching Health Board (PTHB) PGD is based on the UKHSA PGD template v6.0 developed by the following health professionals on behalf of the UKHSA and peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with the UKHSA PGD and Protocol 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)	Christina Wilson Lead Pharmacist – Immunisation Programmes, UKHSA
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Registered Nurse (Chair of Expert Panel)	Greta Hayward Consultant Midwife– Immunisation Programmes, UKHSA

Expert Panel

Name	Designation
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Jess Baldasera	Health Protection Practitioner, North East Health Protection Team, Regions Directorate, UKHSA
Helen Beynon	Clinical Advisor, Immunisation Clinical Advice Response Service (CARS), NHSE London
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Rosie Furner	Advances Specialist Pharmacist, Medicines Governance (Patient Group Directions and Medicines Mechanisms), NHS Specialist Pharmacy Service
Ed Gardner	Advanced Paramedic Practitioner, Emergency Care Practitioner, Primary Care Based, Southbourne Surgery
Shilan Ghafoor	Medicines Governance Pharmacist, Medicines Governance, UKHSA
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PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	6/23/2025
Chief Pharmacist **Jonathan Boyd**	Chief Pharmacist for PTHB	Signed by: Jon Boyd 6D8ECFE8C9EB423...	6/23/2025
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche F07413E114E04B1...	6/23/2025
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	6/25/2025

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 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 vaccinations 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 sections below.** Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD: • 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) • dieticians, occupational therapists, paramedics, physiotherapists and podiatrists currently registered with the Health and Care Professions Council (HCPC) Check Appendix A – Staff Accredited to use the 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 and administration of medicines. Must have completed eLfH PGD eLearning Patient Group Directions training (available via learning@wales, 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 healthcare 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 co-ordinator 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 injection technique • must be competent in the recognition, management and reporting of adverse drug reactions, including anaphylaxis. Must be competent in the administration of adrenaline 1 in 1000 and have up to date Life Support skills (Basic Life Support Skills are PTHB standard; Intermediate Life Support Skills for MIU). • 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)(HepB vaccine). 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/or the UKHSA, NHS England (NHSE) 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 considered at increased risk of exposure to hepatitis B virus, at increased risk of complications of hepatitis B disease, or after a potential exposure to hepatitis B virus in accordance with the recommendations given in Chapter 7 and Chapter 18 of Immunisation Against Infectious Disease: the Green Book. **If used in PTHB Occupational Health Service, the PGD must be used in line with PTHB Occupational Health Immunisation policy.** **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	**Post-exposure** Individuals who: • are babies born to women living with hepatitis B infection

	• have been potentially exposed to hepatitis B infected blood or body fluids **Pre-exposure** Individuals who: • have chronic liver disease (for instance those who have severe liver disease, such as cirrhosis of any cause, or have milder liver disease and may share risk factors for acquiring hepatitis B infection, such as individuals with chronic hepatitis C) • receive regular blood or blood products (for example individuals with haemophilia, thalassaemia or other chronic anaemia) or carers who administer such products • inject drugs or those who are likely to progress to injecting (see the Green Book Chapter 18) • are sexual partners, children, or other close family or household contacts of people who inject drugs (PWID) • change sexual partners frequently, are men who have sex with men (MSM) or commercial sex workers • are household, close family or sexual contacts of an individual with hepatitis B infection • are members of a family adopting children from countries with a high or intermediate prevalence of hepatitis B • are, or are close family or household of, short-term foster carers who receive emergency placements • are, or are close family or household of, permanent foster carers who accept a child known to be hepatitis B infected • are inmates of custodial institutions in the UK, including those on remand • are resident in accommodation for those with learning disabilities • are adults or children attending day care, schools and centres for those with learning disabilities and based on local risk assessment, are at risk of percutaneous exposure (such as biting or being bitten) on a regular basis When used by PTHB Occupational Health Service, for their own staff (including students and trainees), who: • May have direct contact with patients' blood, blood-stained body fluids or tissues

	• Are at risk of injury from blood-contaminated sharp instruments, or of being deliberately injured or bitten by patients. **Incomplete immunisation: routine childhood schedule** Children born on or after 1 August 2017 who: • are identified as having an incomplete immunisation status against hepatitis B and require vaccination in accordance with vaccination of individuals with uncertain or incomplete immunisation status 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 PGDs remit and another form of authorisation will be required)	Individuals for whom no valid consent has been received (or for whom 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. Several resources are available to inform consent (see written information to be given to individual or carer section). Individuals who: • have had a confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine or to any components of the vaccine, which includes yeast in HEPLISAV B®. • are known to have markers of current (HBsAg) or past (anti-HBcore) hepatitis B infection • are on haemodialysis, renal transplantation programmes or have chronic renal failure (See PGD 0175 – Hepatitis B (Renal)) • require HepB vaccination solely for the purpose of overseas travel

	• are solely at an occupational risk of hepatitis B exposure (except when administered by PTHB occupational health department to their own staff) • 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 section "Action to be taken if the individual is excluded" or "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 premises (see Chapter 8 of the Green Book and advice issued by the Resuscitation Council UK). Premature infants should have their immunisations at the appropriate chronological age, according to the schedule. This is vital for infants born to women with hepatitis B infection, as delay will increase the chance of infection being acquired. However, the occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. Therefore, very premature infants (born ≤ 28 weeks of gestation) who are in hospital should have respiratory monitoring for 48 to 72 hours when given their first immunisation, particularly those with a previous history of respiratory immaturity. If the infant has apnoea, bradycardia or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48 to 72 hours. If however, the premature infant was stable at discharge and has no history of apnoea and/or respiratory compromise, further vaccinations may be given in the community setting. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. 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 procedures are in place to avoid injury from faints.

	Use caution when vaccinating individuals with severe (that is, anaphylactic) allergy to latex. The HBvaxPRO® syringe plunger, stopper and tip cap contain 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, reimmunisation 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	Explain reason to individual / carer. Individuals who have had a confirmed anaphylactic reaction to a previous dose of HepB 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 are on haemodialysis, renal transplantation programmes or with chronic kidney disease and anticipated to require haemodialysis or transplant, should be offered HepB vaccination but this is outside the remit of this PGD. For vaccination of renal individuals over 15 years, see PGD 0175 – Hepatitis B Vaccine (Renal). For individuals under 15 years, refer for specialist advice and manage under a PSD as appropriate. Individuals requiring HepB vaccination solely for overseas travel purposes should be administered HepB in accordance with local policy. However, HepB immunisation for travel is not remunerated by the NHS as part of additional services and is therefore not covered by this PGD. Where an individual also requires HepA vaccination, it may be appropriate to provide the combined HepA and HepB vaccine (see the PTHB HepA/B vaccine PGD 0238). Individuals who are solely at occupational risk of hepatitis B exposure should be referred to their employer's occupational health provider for vaccination. (NB. PTHB occupational health department may work to this PGD for their own staff). In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity. Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required. 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. For PTHB occupational Health Service- refer to Occupational Health Consultant as necessary and

	document advice given in the individual's occupational health records.
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. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent, see Chapter 2 of the Green Book. The patient information leaflet should be available to inform consent. All cases, where HepB vaccination is declined on behalf of infants born to women living with hepatitis B infection, should be contemporaneously referred in line with the guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway). Advise the individual, parent or 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. For PTHB occupational Health Service- refer to Occupational Health Consultant as necessary and document advice given in the individual's occupational health records.
Arrangements for referral for medical advice	Refer to GP, paediatrician, consultant in communicable disease control (CCDC) or the PTHB occupational health consultant 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): • Engerix B® 10micrograms/0.5ml suspension for injection in pre-filled syringe • Engerix B® 20micrograms/1ml suspension for injection in pre-filled syringe • HBvaxPRO® 5micrograms/0.5ml suspension for injection in pre-filled syringe • HBvaxPRO® 10micrograms/1ml suspension for injection in pre-filled syringe • HEPLISAV B® 20 micrograms/ 0.5ml solution for injection in a pre-filled syringe An appropriate vaccine product should be selected for the individual to be treated (see Dose and Frequency of Administration).
Legal category	Prescription only medicine (POM)
Black triangle▼	Yes, 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.
Off-label use	The full 1ml volume of adult preparations of Engerix B® and HBvaxPRO® vaccines may be given to children off-label, during paediatric hepatitis B-containing vaccine supply shortages, in accordance with Hepatitis B: vaccine recommendations during supply constraints. As there is little or no data pertaining to use of HEPLISAV B® in the paediatric population, it should not be given to individuals under 18 years. Whilst it is preferable that the same vaccine brand is used throughout the course, HEPLISAV B® may be given to individuals over 18 years if the brand used for the first dose is not available, to avoid a delay in protection. Engerix B® very rapid (super accelerated) 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 (this includes PWID and those in prison) in accordance with Chapter 18 of the Green Book. Vaccines 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 or any subsequent UKHSA update. Where vaccines are 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 or carer that the vaccine is being offered in accordance with national guidance but outside of product licence.
Route and method of administration	Administer by intramuscular injection into the deltoid muscle of the upper arm for individuals over one year of age and the anterolateral aspect of the thigh for infants (see 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 the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into 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. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can be vaccinated via the intramuscular route. If the individual receives medication or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after

	such medication or other treatment is administered. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual, parent or carer should be informed about the risk of haematoma from the injection. For individuals with an unstable bleeding disorder (or where intramuscular injection is otherwise not considered suitable), vaccines normally given by the intramuscular route should be given by deep subcutaneous injection, in accordance with the recommendations in the Green Book Chapter 4. Take care to select the correct vaccine - some vaccines have look-alike and sound-alike presentations. Check correct vaccine has been selected prior to administration. The vaccine may settle during storage. Shake the vaccine well before administration to obtain a slightly opaque (HBvaxPro®) or turbid (Engerix B®), white suspension. HEPLISAV B® is a solution and does not require shaking before administration. The vaccine should be visually inspected for foreign particulate matter and variation of expected appearance prior to preparation and administration. Should either occur, discard the vaccine in accordance with local procedures. The vaccine SPC provides further guidance on preparation and administration.
Dose and frequency of administration (Note: This section is reproduced in Appendix B for clarity and ease of reference)	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. **(i) Pre and post exposure prophylaxis** Post-exposure prophylaxis should be initiated rapidly. Babies born to women with hepatitis B infection should receive the first dose of vaccine as soon as possible, ideally within 24 hours of birth.

Table 1 below lists the current UK licensed HepB vaccines and dosage by age.

Table 2 provides recommended pre-and post-exposure schedules.

Individuals who require other vaccines at the same time as a scheduled HepB dose may receive these as separate vaccine products or the scheduled HepB dose may be fulfilled by the administration of a multivalent vaccine, such as HepA/HepB combined vaccine or DTaP/IPV/Hib/HepB (see PTHB HepA/B vaccine PGD 0238 or PTHB Hexavalent DTaP/IPV/Hib/HepB PGD 0141 as appropriate).

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

Table 1: Current UK licensed HepB vaccine doses

Age	Vaccine	Dose	Volume
0–15 years*	Engerix B®**	10 micrograms	0.5ml
	HBvaxPRO®**	5 micrograms	0.5ml
16 years or over	Engerix B®	20* micrograms	1.0ml
	HBvaxPRO®	10 micrograms	1.0ml
18 years or over	HEPLISAV B®	20 micrograms	0.5ml

*20 micrograms of Engerix B® may be given to children 11 to 15 years of age if using the two dose schedule.

**During supply shortages of paediatric hepatitis B containing vaccine, the full 1ml adult preparation of Engerix B® or HBvaxPRO® vaccines may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk (see additional information). These adult preparations may be used interchangeably with the paediatric products until vaccine becomes available (see additional information for order of preference).

Table 2: Pre- and post-exposure prophylaxis schedules

Schedule number	Schedule	Examples of when to use this schedule
1	**Usual pre- and post-exposure prophylaxis accelerated schedule**: • 3 doses at 0, 1, and 2 months • further dose 12 months after the first dose for babies born to women with hepatitis B infection **with a date of birth on or before 30 June 2024** and individuals at continued high risk **HBvaxPRO® 5 and 10 micrograms and Engerix B®**	Used for individuals of all ages for pre- and post-exposure prophylaxis. This is the preferred schedule for babies born to women with hepatitis B infection, **born on or before 30 June 2024**. Note: dose from 2 months of age may be provided by multivalent vaccine, such as DTaP/IPV/Hib/HepB, and doses may be administered in addition to this schedule where DTaP/IPV/Hib/HepB is used for routine childhood immunisation.
2	**Alternative schedule**: • 3 doses at 0, 1, and 6 months **Engerix B® and HBvaxPRO®**	This schedule should be used when rapid protection is not required and there is a high likelihood of compliance with the regimen.
3	**2 dose schedule of Engerix B® only:** • 2 doses of adult strength (20 microgram) vaccine at 0 and 6 months	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.
4	**Very rapid (super accelerated) schedule of Engerix B® only:** • 3 doses at 0, 7 days and 21 days • further dose 12 months after the first dose is recommended to be considered protected	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 such as PWID or prisoners.
5	**2 dose schedule for HEPLISAV B®** • 2 doses at 0 and 1 month	Only for individuals aged 18 years and over.

*Note: Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate. This PGD does

	not cover the administration of multivalent vaccines and therefore a PSD should be used. (ii) **Incomplete immunisation: routine childhood schedule** Individuals born from 1 August 2017, who received primary vaccination without Hep B vaccine should be offered up to 3 doses course of monovalent HepB vaccine. The individual should be offered up to 3 doses of HepB vaccine appropriate to the individual's age as outlined in Table 1. The vaccination schedule appropriate to the individual's circumstances (Table 2) should be used. In most cases, either Schedule 1 or 2 will be appropriate. **(iii) Reinforcing immunisation** The current UK recommendation 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 HepB-containing vaccine, except in the following cases: • at the time of a subsequent significant exposure – see the Green Book Chapter 18, Table 18.8 (Hepatitis B prophylaxis for reported exposure incidents). Vaccination is covered by this PGD. • individuals with renal failure (see Hep B renal PGD 0175) • healthcare and laboratory workers (including students and trainees) under the care of PTHB occupational health department who have not responded to the primary course (refer to the Green book chapter 18 'Testing for evidence of immunity after vaccination' for details) Either HBvaxPro® or Engerix B® should be offered for reinforcing doses, as HEPLISAV B® is not licensed for reinforcing immunisation.
Duration of treatment	Dependent on vaccine schedule. See dose and frequency of administration
Quantity to be administered	Dose of 0.5ml or 1.0ml per administration depending on the age of the individual and vaccine product used. See dose and frequency of administration.

Supplies	Supplies should be ordered directly from manufacturers or their wholesalers. Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the Green Book Chapter 3). Also refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines.
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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. In accordance with the SPC, HBvaxPRO® 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 that 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. In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to All Wales Advisory document on Ordering Storage and Handling of Vaccines and Vaccine Incident Guidance or any subsequent UKHSA update. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.

	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 Once for Wales Reporting System.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste 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 waste disposal arrangements and NHSE guidance (HTM 07-01): safe and sustainable management of healthcare waste and guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste.
Drug interactions	The immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited. May be given at the same time as other vaccines. A detailed list of drug interactions is available from the vaccine's SPC.
Identification and management of adverse reactions	Local reactions following vaccination are very common such as pain, swelling or redness at the injection site, induration. Low grade fever, fatigue, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after HepB vaccination. Headache and myalgia are very common side effects specific to HEPLISAV B®. Hypersensitivity reactions and anaphylaxis can occur but are very rare. A detailed list of adverse reactions is available from the product's SPC.

	Report any suspected adverse reactions to a doctor. 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) PGD 0017 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 individual's notes • Ensure all individual's records are marked **ALLERGIC TO Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed). State the brand of vaccine administered.** • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers • Report via Datix Once for Wales Reporting System.
Reporting procedure of adverse reactions	Healthcare professionals and individuals, parents and carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or by searching 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 the marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Immunisation promotional material may be provided as appropriate: • protecting your baby against hepatitis B • hepatitis B: a guide to your care in pregnancy and after your baby is born Further information for printing and website links suitable for patients 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 or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SPC.
Advice and follow-up treatment	Give appropriate advice if medication is used off-label. Inform the individual, parent or carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site. The individual, parent or carer should be advised to seek medical advice in the event of an adverse reaction and report this via the Yellow Card reporting scheme. When administration is postponed advise the individual, parent or carer when to return for vaccination. 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. Individuals, parents or carers should be informed about the importance of completing a course of hepatitis B immunisation. Women with hepatitis B infection whose babies are on the neonatal hepatitis B immunisation pathway should be informed of the importance of completing the course on time and for baby to be tested. For eligible children born on or after 1 July 2024, testing for HBsAg can be undertaken any time between one year and 18 months of age to identify if they have become chronically infected with hepatitis B. Children born on or before 30 June 2024 should continue to be tested at 12 months (see special considerations and

	additional information section below). (Note: The pre-school vaccinations visit provides an opportunity to check children on the selective neonatal hepatitis B immunisation pathway have been fully immunised against hepatitis B and tested for infection.) **When used by PTHB occupational Health Service for its own staff only** see Green book chapter 18 for relevant advice and follow up treatment.
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 HepB 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 vaccinees (see Chapter 18 for more detail). **Testing for evidence of infection or immunity** Where testing for markers of current or past infection is clinically indicated (such as for sexual and household contacts of hepatitis B infected individuals), this should be done at the same time as the administration of the first HepB vaccine dose. Vaccination should not be delayed while waiting for results of the tests. Further doses may not be required in those with clear evidence of current or past infection. Dried Blood Spot (DBS) testing of children born to women with hepatitis B infection for HBsAg from one year of age will identify any babies for whom vaccination has not been successful and who have become chronically infected with hepatitis B. This will allow them to be referred for assessment and for any further management. For children **born on or before 30 June 2024**, DBS testing should be carried out at the same time as the 12

	month vaccine dose is given as outlined in Schedule 1 (see Table 2). For children **born on or after 1 July 2024**, DBS testing can be carried out at any time between 12 and 18 months of age, such as at opportunistic or routine healthcare appointments. The 12 month dose of monovalent hepatitis B vaccine should not be offered to these children. Instead, these children will receive a dose of hexavalent vaccine at 18 months of age, given as part of the routine childhood immunisation schedule. See the DTaP/IPV/Hib/HepB (hexavalent) PGD0141 for more information. Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be completed, but it is more likely the child may become infected. In this instance, testing for HBsAg between 12 and 18 months of age is particularly important. Additional vaccine doses may need to be considered for individuals who do not respond or have a sub-optimal response to a course of vaccinations. Except in certain groups (such as for risk of occupational exposure and renal failure), testing of anti-HBs is not routinely recommended. Refer to the Green Book Chapter 18 for advice on response to the vaccine and the use of additional doses. Testing of anti-HBs is routinely recommended in those at risk of occupational exposure; anti-HBs titres should be checked one to two months after the completion of a primary course of vaccine. Additional vaccine doses may need to be considered for individuals who do not respond or have a sub-optimal response to a course of vaccinations. Refer to The Green Book Chapter 18 for further details, advice on response to the vaccine and the use of additional doses. **Post-exposure prophylaxis** A summary of guidance is given in the Green Book Chapter 18 Table 18.8 (Hepatitis B prophylaxis for reported exposure incidents). **Hepatitis B immunoglobulin (HBIG)** This PGD does not cover the administration of HBIG.

	Whenever immediate hepatitis B protection is required, hepatitis B containing vaccine should be given. When appropriate, this should be combined with simultaneous administration of HBIG at a different site. For more information, see the Green Book Chapter 18 Table 18.8 (Hepatitis B prophylaxis for reported exposure incidents). The use of HBIG in addition to vaccine is recommended post-exposure only in high-risk situations or in a known non-responder to vaccine. HBIG should be given as soon as possible, ideally at the same time or within 24 hours of the vaccine, although HBIG should still be considered up to a week after exposure. Any sexual partner of individuals suffering from acute hepatitis B and who are seen within one week of last contact, should be offered protection with HBIG and vaccine. Sexual contacts of an individual with newly diagnosed chronic hepatitis B should be offered vaccine; HBIG may be added if unprotected sexual contact occurred in the past week. All babies born to women living with hepatitis B infection, with a birthweight of 1500g or less, or where the mother's test results for e-markers and viral load indicate a high infectivity risk, should receive HBIG as well as active immunisation (see Chapter 18, Table 18.6: vaccination of babies according to the hepatitis B status of the pregnant woman). HBIG may be given simultaneously with the vaccine but at a different site. **Dosing of hepatitis B for people living with HIV** Administration of a higher dose of hepatitis B vaccine (40 micrograms) than recommended in Table 1 is one of the suggested management strategies for people living with HIV (see Chapter 18 of the Green Book and BHIVA guidance).Where a clinician has deemed it appropriate to administer a 40 microgram dose, this is outside the scope of this PGD and should be administered under a PSD instead. **Choice of HepB vaccine during supply constraints** During periods of constrained paediatric hepatitis B containing vaccine, the first priority group for paediatric vaccine should be infants in the selective neonatal hepatitis B programme, that is infants born to women with hepatitis B infection receiving post-exposure

	prophylaxis (PEP), followed by other lower risk indications for PEP. Vaccine administration should never be delayed for infants born to women with hepatitis B infection, as these infants have been exposed to a substantial volume of infectious blood during the birthing process. Available vaccine products should be used in the following order of preference: 1. Hepatitis B paediatric monovalent vaccine (Engerix B® 10 microgram in 0.5ml or HBvaxPRO® 5 micrograms in 0.5ml) 2. Hepatitis B adult monovalent vaccine (Engerix B® 20 micrograms in 1.0ml and HBvaxPRO® 10 micrograms in 1.0ml). 3. Combined hepatitis A and B vaccine (see the PTHB HepA/B PGD 0238). The 1 ml adult preparations of HepB vaccine contain exactly twice the content of the paediatric equivalent (see Table 1 above). As the adult pre-filled syringe has no clear graduations, the UKHSA recommends the full 1ml volume (that is an adult dose) should be given if vials are not available, to avoid the risk of under-dosing the child (see doses and volumes in Table 1 above). This will be off-label use of the adult vaccine. Available data, although limited, does not indicate any additional safety risk from use of adult HepB vaccine in infants. If an adult dose(s) of HepB vaccine has been used in a child, the course can be completed with paediatric products at the appropriate ages when vaccine stock becomes available. **Note:** as there is little or no data pertaining to use of HEPLISAV B® in the paediatric population, this vaccine should not be given to individuals under 18 years. **Pregnant or breastfeeding women** There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated vaccines. Since HepB vaccine is inactivated, the risks to the fetus are negligible and it should be given where there is a definite risk of infection. Hepatitis B vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis A, hepatitis C and hepatitis E viruses.

	NB. Consult the PTHB Occupational Health Immunisation policy for staff requiring immunisation.
Records	Record consultation details as required by local procedures. The practitioner must ensure the following is recorded: • 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 (or record where an individual is not registered with a GP) • medical and drug history taken, including any allergies and previous adverse events • 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 password-controlled 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. When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) (Child Health Records Department) using the appropriate documentation or pathway as required by any local or contractual arrangement (based in Brecon Hospital for under 5 years and 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	HepB vaccine • Immunisation Against Infectious Disease: The Green Book Chapter 18 • Summary of Product Characteristic for Engerix B®, GlaxoSmithKline, last updated 27 November 2024 http://www.medicines.org.uk/emc/medicine/9283 • Summary of Product Characteristic for HBVAXPRO® 5micrograms and 10micrograms. MSD Ltd, last updated 3 January 2023 http://www.medicines.org.uk/emc/medicine/9850 http://www.medicines.org.uk/emc/medicine/9847 • Summary of Product Characteristics for HEPLISAV B® 20 micrograms, Dynavax GmBH, last updated 8 October 2024 (accessed via https://products.mhra.gov.uk) • NHS public health functions agreement 2019-20, Service specification No.1 Neonatal hepatitis B immunisation programme. July 2019. https://www.england.nhs.uk/wp-content/uploads/2020/02/Service-Specificaiton-No.01-Neonatal-HepB.pdf • Hepatitis B: vaccine recommendations during supply constraints. Public Health England, last updated 20 November 2018. https://www.gov.uk/government/publications/hepatitis-b-vaccine-recommendations-during-supply-constraints • Hepatitis B: clinical and public health management https://www.gov.uk/guidance/hepatitis-b-clinical-and-public-health-management • Changes to the routine childhood vaccination schedule from 1 July 2025 and 1 January 2026 letter, published 30 April 2025 https://www.gov.uk/government/publications/changes-to-the-routine-childhood-schedule-letter • WHC 2025/019 Changes to routine childhood and selective neonatal hepatitis B vaccinations. May 2025 **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/manage

	ment-and-disposal-of-healthcare-waste-htm-07-01/ • National Minimum Standards and Core Curriculum for Immunisation Training, published 7 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 27 March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions, updated 4 January 2018 https://www.nice.org.uk/guidance/mpg2/resources • UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation • Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Protocol for ordering storage and handling of vaccines. April 2014. https://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.

Appendix B

Table 1: Current UK licensed HepB vaccine doses

Age	Vaccine	Dose	Volume
0–15 years*	Engerix B®**	10 micrograms	0.5ml
	HBvaxPRO®**	5 micrograms	0.5ml
16 years or over	Engerix B®	20* micrograms	1.0ml
	HBvaxPRO®	10 micrograms	1.0ml
18 years or over	HEPLISAV B®	20 micrograms	0.5ml

*20 micrograms of Engerix B® may be given to children 11-15 years of age if using the two dose schedule.

**During supply shortages of paediatric hepatitis B containing vaccine, the full 1ml adult preparation of Engerix B® and HBvaxPRO® vaccines may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk (see Additional Information). These adult preparations may be used interchangeably with the paediatric products until vaccine becomes available (see Additional Information for order of preference).

Table 2: Pre- and post-exposure prophylaxis schedules

Schedule number	Schedule	Examples of when to use this schedule
1	**Usual pre- and post-exposure prophylaxis accelerated schedule:** • 3 doses at 0, 1, and 2 months • further dose 12 months after the first dose for babies born **on or before 30 June 2024**, to women with hepatitis B infection and individuals at continued high risk • **Engerix B® or HBvaxPRO®** 5 and 10 micrograms	Used for individuals of all ages for pre- and post-exposure prophylaxis. This is the preferred schedule for babies **with a date of birth on or before 30 June 2024**, born to women with hepatitis B infection. Note: dose from 2 months of age may be provided by multivalent vaccine, such as DTaP/IPV/Hib/HepB, and doses may be administered in addition to this schedule where DTaP/IPV/Hib/HepB is used for routine childhood immunisation.
2	**Alternative schedule:** • 3 doses at 0, 1, and 6 months • **Engerix B® or HBvaxPRO®**	This schedule should be used when rapid protection is not required and there is a high likelihood of compliance with the regimen.
3	**Two dose schedule of Engerix B® only:** • 2 doses of adult strength (20 microgram) vaccine at 0 and 6 months	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.
4	**Very rapid (super-accelerated) schedule of Engerix B® only:** • 3 doses at 0, 7 days and 21 days • further dose 12 months after the first dose is recommended to be considered protected	To be used for individuals from 16 years of age (see Off-label use) when very rapid immunisation is required, such as PWID or prisoners
5	**2 dose schedule for HEPLISAV B®** 2 doses at 0 and 1 month	Only for individuals aged 18 years and over.
	Booster (Engerix B®, HBvaxPro®): The current UK recommendation 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 HepB-containing vaccine, except in the following: • at the time of a subsequent significant exposure - see Table 18.8 of Chapter 18 (covered by this PGD) • individuals with renal failure (see PTHB Hep B renal PGD 0175)	

Note: Scheduled HepB vaccine doses may be fulfilled by multivalent vaccine when appropriate. This PGD does not cover the administration of multivalent vaccines.