UK Health Security Agency

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Hepatitis B vaccine Patient Group Direction (PGD)

This PGD is for the administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) 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.

This PGD is for the administration of Hepatitis B (rDNA) vaccine (adsorbed) (HepB vaccine) by registered healthcare professionals identified in section 3, subject to any limitations to authorisation detailed in section 2.

Reference no:	HepB vaccine PGD
Version no:	v6.0
Valid from:	1 July 2025
Review date:	31 October 2027
Expiry date:	30 April 2028

The UK Health Security Agency (UKHSA) has developed this PGD to facilitate the delivery of publicly funded immunisation in England, in line with national recommendations. Those using this PGD must ensure that it is organisationally authorised and signed in Section 2 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**.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. In addition, authorising organisations must not alter section 3 (Characteristics of staff). **Sections 2 and 7 can be edited within the designated editable fields provided, but only for the purposes for which these sections are provided, namely the responsibilities and governance arrangements of the NHS organisation using the PGD. The fields in section 2 and 7 cannot be used to alter, amend or add to the clinical content. Such action will invalidate the UKHSA clinical content authorisation which is provided in accordance with the regulations**.

Operation of this PGD is the responsibility of commissioners and service providers. The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 8 years after the PGD expires if the PGD relates to adults only and for 25 years after the PGD expires if the PGD relates to children only, or adults and children. Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

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. Current versions of UKHSA PGD templates for authorisation can be found from:
Immunisation patient group direction (PGD) templates

[1] This includes any relevant amendments to legislation

Any concerns regarding the content of this PGD should be addressed to: immunisation@ukhsa.gov.uk

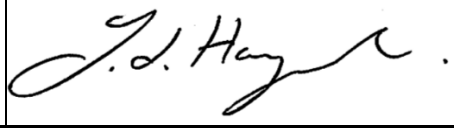
Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: england.swvast@nhs.net

Change history

Version number	Change details	Date
v1.0 and v2.0	See previous PGDs for details of changes made	29 March 2017 to 9 April 2021
v3.0	HepB PGD amended to: • 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 women with hepatitis B infection 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	9 April 2021
v4.0	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	8 October 2021
v5.0	UKHSA Hepatitis B vaccine PGD amended 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	9 October 2023
v6.0	UKHSA Hepatitis B vaccine PGD amended 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	2 June 2025

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Christina Wilson Lead Pharmacist – Immunisation Programmes, UKHSA		21 May 2025
Doctor	Dr Sema Mandal Deputy Director and Consultant Epidemiologist, Blood Safety, Hepatitis, STIs and HIV, UKHSA		21 May 2025
Registered Nurse (Chair of Expert Panel)	Greta Hayward Consultant Midwife– Immunisation Programmes, UKHSA		21 May 2025

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with UKHSA PGD and Protocol Policy. It has been ratified by the UKHSA Medicines Governance Committee.

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
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Jodie Crossman	Clinical Nurse Specialist – GU Medicine, Brighton SHAC and Co-chair – Sexually Transmitted Infections Foundation
Helen Eley	Lead Immunisation Nurse Specialist - Immunisation Programmes, UKHSA
Jane Freeguard	Deputy Director of Vaccination – Medicines and Pharmacy, NHSE
Rosie Furner	Advanced 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
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
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Dr Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Tushar Shah	Lead Pharmacy Adviser, NHSE London

2. Organisational authorisations

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.

NHS England (South West)authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
All NHS England commissioned immunisation services within • Bath & North East Somerset, Swindon, and Wiltshire • Bristol, North Somerset, and South Gloucestershire • Cornwall and the Isles of Scilly • Devon • Dorset • Gloucestershire • Somerset
Limitations to authorisation
This patient group direction (PGD) must only be used by the registered healthcare practitioners identified in Section 3 who have been named by their organisation to practice under it. The most recent in-date final version authorised by NHS England (South West) must be used. This PGD includes vaccination of individuals across the national immunisation programme. Users of this PGD should note that where they are commissioned to immunise certain groups this PGD does not constitute permission to offer immunisation beyond the groups they are commissioned to immunise

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Deputy Medical Director for Primary Care and Responsible Officer, South West Region, NHSE	Dr Rupa Joshi		10 June 2025

Additional signatories according to locally agreed policy			
Role	**Name**	**Sign**	**Date**

Local enquiries regarding the use of this PGD may be directed to england.swvast@nhs.net

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in

accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD.

3. 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 section 2 (Limitations to authorisation) 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 be competent in the use of PGDs (see NICE competency framework for healthcare professionals using PGDs) • 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 • 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 • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis • 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	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 should be constantly alert to any subsequent recommendations from 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.

4. 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
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 **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
Criteria for exclusion[2]	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).

[2] 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.

Criteria for exclusion (continued)	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 HepB Renal PGD) • require HepB vaccination solely for the purpose of overseas travel • are solely at an occupational risk of hepatitis B exposure • are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)
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.
Action to be taken if the individual is excluded (continued over page)	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.

Action to be taken if the individual is excluded (continued)	For vaccination of renal individuals over 15 years, see the HepB Renal PGD. 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 UKHSA HepA/B vaccine PGD). Individuals who are solely at occupational risk of hepatitis B exposure should be referred to their employer's occupational health provider for vaccination. 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.
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. 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.
Arrangements for referral for medical advice	As per local policy

5. 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 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 (continued over page)	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. 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

Route and method of administration

(continued)

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.

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 the appendix 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 the UKHSA HepA/B vaccine PGD or UKHSA hexavalent DTaP/IPV/Hib/HepB PGD 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® 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

(continued over page)

Dose and frequency of administration (continued)

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.

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Dose and frequency of administration (continued)	*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) 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 supplied and 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).
Storage	Store at between +2°C to +8°C. Store in original packaging in order to protect from light. Do not freeze. 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 Vaccine Incident Guidance or any subsequent UKHSA update. Contact the vaccine manufacturer where more specific advice is required about managing a temperature excursion.

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.
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.
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.
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 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 (continued over page)	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.

Advice and follow-up treatment (continued)	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.)
Special considerations and additional information (continued over page)	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a 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) PGD 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. **Post-exposure prophylaxis**

Special considerations and additional information (continued)	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 within 48 hours, 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 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 UKHSA HepA/B PGD). The 1ml 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.

(continued over page)

Special considerations and additional information (continued)	**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.
Records	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 • 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) • name 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 • supplied via PGD 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) using the appropriate documentation or pathway as required by any local or contractual arrangement. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

6. Key references

Key references	**HepB vaccine** • Immunisation Against Infectious Disease: The Green Book Chapter 18 • Summary of Product Characteristics for Engerix B®, GlaxoSmithKline, last updated 27 November 2024 http://www.medicines.org.uk/emc/medicine/9283 • Summary of Product Characteristics for HBVAXPRO® 5 micrograms and 10 micrograms, 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 **General** • NHSE Health Technical Memorandum 07-01: safe and sustainable management of healthcare waste, updated 7 March 2023 https://www.england.nhs.uk/publication/management-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

7. Practitioner authorisation sheet

HepB vaccine PGD v6.0 Valid from: 1 July 2025 Expiry: 30 April 2028

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Practitioner

By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

Patient group directions 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.			
Name	Designation	Signature	Date

Authorising manager

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

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this PGD.

Appendix

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 Hep B renal PGD)

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