UK Health Security Agency

**UKHSA publications gateway number: GOV-10119**

# 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.

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| Reference no: | HepB PGD |
| Version no: | v04.00 |
| Valid from: | 01 November 2021 |
| Review date: | 01 May 2023 |
| Expiry date: | 31 October 2023 |

**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'. Only sections 2 and 7 can be amended within the designated editable fields provided.

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 PHE/UKHSA PGD templates for authorisation can be found from:
https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd

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

[1] This includes any relevant amendments to legislation (eg 2013 No.235, 2015 No.178 and 2015 No.323).

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to:

The Screening and Immunisation Team, NHS England and NHS Improvement – Midlands, responsible for your area:

**East** (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) **england.emids-imms@nhs.net**

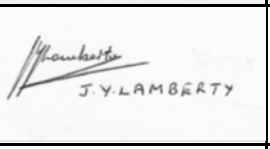
**West** (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire)
**england.wmid-imms@nhs.net**

## Change history

| Version number | Change details | Date |
|---|---|---|
| V01.00 | New PHE PGD template | 29/03/2017 |
| V02.00 | HepB PGD amended to:<br>• include additional healthcare practitioners in Section 3<br>• include HBvaxPRO® temperature excursion stability<br>• refer to vaccine incident guidelines in off-label and storage sections<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs | 12/03/2019 |
| V03.00 | HepB PGD amended to:<br>• include chronic anaemia and those on remand in the inclusion criteria<br>• include 'best-interests' decision in accordance with the Mental Capacity Act 2005, for consent<br>• remove Engerix B® 20microgram/1ml suspension for injection vials, which have been discontinued<br>• 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.<br>• reflect changes to 'The Green Book' recommendations for booster doses<br>• include stability data for Engerix B®<br>• 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.<br>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs and updated references | 09/04/2021 |
| V04.00 | HepB PGD amended to:<br>• removal of reference to booster doses for healthcare workers<br>• include minor rewording, layout and formatting changes for clarity and consistency with other UKHSA PGDs and updated references | 08/10/2021 |

## 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) | Jacqueline Lamberty<br>Lead Pharmacist Medicines Governance, UKHSA |  | 12 October 2021 |
| **Doctor** | Dr Gayatri Amirthalingam<br>Consultant Epidemiologist, Immunisation, Hepatitis and Blood Safety Department, National Infection Service, UKHSA |  | 12 October 2021 |
| **Registered Nurse** (Chair of Expert Panel) | David Green<br>Nurse Consultant – Immunisation and Countermeasures, UKHSA |  | 12 October 2021 |

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

**Expert Panel**

| Name | Designation |
|---|---|
| Nicholas Aigbogun | Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA |
| Sarah Dermont | Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHS England and NHS Improvement |
| Ed Gardner | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead |
| Michelle Jones | Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG |
| Vanessa MacGregor | Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA |
| Alison Mackenzie | Consultant in Public Health Medicine /Screening and Immunisation Lead, NHS England and NHS Improvement South (South West) |
| Gill Marsh | Principal Screening and Immunisation Manager NHS England and NHS Improvement (North West) |
| Lesley McFarlane | Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHS England and NHS Improvement (Midlands) |
| Tushar Shah | Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region) |

## 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 and NHS Improvement - Midlands** authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisations and/or services |
|---|
| **Primary care services and all organisations commissioned or contracted by NHS England and NHS Improvement – Midlands to provide immunisation services in: Derbyshire, Nottinghamshire, Leicestershire, Lincolnshire, Northamptonshire, Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton and Worcestershire** |
| Limitations to authorisation |
| |

| **Organisational approval (legal requirement)** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
| NHS England and NHS Improvement, Acting Director of Primary Care and Public Health Commissioning - Midlands | Richard Yeabsley |  | 22/10/2021 |

| **Additional signatories according to locally agreed policy** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
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Local enquiries regarding the use of this PGD may be directed to:

The Screening and Immunisation Team, NHS England and NHS Improvement – Midlands, responsible for your area:

**East** (Derbyshire & Nottinghamshire and Leicester, Leicestershire, Rutland, Lincolnshire & Northamptonshire) **england.emids-imms@nhs.net**

**West** (Shropshire, Staffordshire, Birmingham, Coventry, Dudley, Herefordshire, Sandwell, Solihull, Walsall, Warwickshire, Wolverhampton & Worcestershire) **england.wmid-imms@nhs.net**

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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

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| **Qualifications and professional registration** | Registered professional with one of the following bodies:<br>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)<br>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)<br>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)<br><br>The practitioners above must also fulfil the Additional requirements detailed below.<br><br>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:<br>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it<br>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines<br>• must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs)<br>• 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<br>• 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<br>• must be competent to undertake immunisation and to discuss issues related to immunisation<br>• must be competent in the handling and storage of vaccines, and management of the 'cold chain'<br>• must be competent in the recognition and management of anaphylaxis<br>• must have access to the PGD and associated online resources<br>• should fulfil any additional requirements defined by local policy<br><br>**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).<br><br>Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHS England and NHS Improvement and other sources of medicines information.<br>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

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| **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**<br>Individuals who:<br>• are babies born to hepatitis B infected mothers<br>• have been potentially exposed to hepatitis B infected blood or body fluids<br>**Pre-exposure**<br>Individuals who:<br>• 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)<br>• receive regular blood or blood products (for example individuals with haemophilia, thalassaemia or other chronic anaemia) or carers who administer such products<br>• inject drugs or those who are likely to progress to injecting (see 'The Green Book' Chapter 18)<br>• are sexual partners, children, or other close family or household contacts of people who inject drugs (PWID)<br>• change sexual partners frequently, are men who have sex with men (MSM) or commercial sex workers<br>• are household, close family or sexual contacts of an individual with hepatitis B infection<br>• are members of a family adopting children from countries with a high or intermediate prevalence of hepatitis B<br>• are, or are close family or household of, short-term foster carers who receive emergency placements<br>• are, or are close family or household of, permanent foster carers who accept a child known to be hepatitis B infected<br>• are inmates of custodial institutions in the UK, including those on remand<br>• are resident in accommodation for those with learning disabilities<br>• 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 |
| **Criteria for exclusion**[2]<br><br>Continued over page<br>**Criteria for exclusion** | Individuals for whom valid consent, or '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'). The Patient information leaflet (PIL) for the vaccine to be used should be available to inform consent. |

[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.

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| (continued) | Individuals who:<br>• have had a confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine or to any components of the vaccine<br>• are known to have markers of current (HBsAg) or past (anti-HBcore) hepatitis B infection<br>• are on haemodialysis, renal transplantation programmes or have chronic renal failure (See HepB Renal PGD)<br>• require HepB vaccination solely for the purpose of overseas travel<br>• are solely at an occupational risk of hepatitis B exposure<br>• 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** | Premature infants should have their immunisations at the appropriate chronological age, according to the schedule. This is vital for infants born to hepatitis B infected mothers, 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 48-72 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 48-72 hours. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.<br><br>Syncope (fainting) can occur following, or even before, any vaccination, especially in adolescents, as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important procedures are in place to avoid injury from faints.<br><br>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.<br><br>The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate. |
| **Action to be taken if the patient is excluded**<br><br>continued over page<br>**Action to be taken if the patient is excluded** (continued) | 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.<br><br>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.<br><br>Individuals who are on haemodialysis, renal transplantation programmes or with chronic kidney disease and anticipated to |

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| | require haemodialysis or transplant, should be offered HepB vaccination but this is outside the remit of this PGD. For vaccination of renal patients over 15 years: see HepB Renal PGD. For individuals under 15 years: refer for specialist advice and manage under PSD as appropriate.<br><br>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).<br><br>Individuals who are solely at occupational risk of hepatitis B exposure should be referred to their employer's occupation health provider for vaccination.<br><br>Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged.<br><br>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.<br><br>The risk to the individual of not being immunised must be taken into account.<br><br>Document the reason for exclusion and any action taken in the individual's clinical records.<br><br>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. |
| **Action to be taken if the patient 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'.<br><br>All cases, where HepB vaccination is declined on behalf of infants born to hepatitis B infected mothers, should be contemporaneously referred (see Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway).<br><br>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.<br><br>Document the advice given and the decision reached.<br><br>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

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| **Name, strength & formulation of drug** | Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) (HepB) eg:<br>• Engerix B® 10micrograms/0.5ml suspension for injection in pre-filled syringe<br>• Engerix B® 20micrograms/1ml suspension for injection in pre-filled syringe<br>• HBvaxPRO® 5micrograms/0.5ml suspension for injection in pre-filled syringe<br>• HBvaxPRO® 10micrograms/1ml suspension for injection in pre-filled syringe<br>An appropriate vaccine product should be selected for the patient group to be treated see Dose and Frequency of Administration. |
| **Legal category** | Prescription only medicine (POM) |
| **Black triangle▼** | No |
| **Off-label use** | The full 1ml volume of adult preparations of HepB vaccine may be given to paediatric patients off-label, during paediatric hepatitis B containing vaccine supply shortages, in accordance with the PHE recommendations, see Hepatitis B: vaccine recommendations during supply constraints.<br>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'.<br>Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance or any subsequent UKHSA update. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.<br>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. |
| **Route / method of administration**<br><br>Continued over page | Administer by intramuscular injection into the deltoid region of the upper arm for individuals over one year of age and the anterolateral thigh for infants. The buttock should not be used because vaccine efficacy may be reduced.<br>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 in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.<br>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous |

**Route / method of administration** (continued)

injection to reduce the risk of bleeding (see 'The Green Book' Chapter 4).

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

The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

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

**Dose and frequency of administration**

(Note: This section is reproduced in Appendix A 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.

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.

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

Table 2 overleaf 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 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 |

*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 hepatitis B containing vaccine may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk (see Additional Information). The adult preparations may be used interchangeably with the paediatric products when vaccine becomes available (see Additional Information for order of preference).

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**Dose and frequency of administration** (continued)

**Table 2: Pre- and post-exposure prophylaxis schedules for Engerix B® or HBvaxPRO®**

| Schedule | Examples of when to use this schedule |
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| **Usual pre- and post-exposure prophylaxis accelerated schedule***:<br>• 3 doses at 0, 1, and 2 months<br>• further dose 12 months after the first dose for babies born to hepatitis B infected mothers and individuals at continued high risk | Used for individuals of all ages for pre- and post-exposure prophylaxis.<br>This is the preferred schedule for babies born to hepatitis B infected mothers. 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. |
| **Alternative schedule***:<br>• 3 doses at 0, 1, and 6 months | This is rarely the most appropriate schedule. It should only be used when rapid protection is not required and there is a high likelihood of compliance with the regimen. |
| **Two dose schedule of Engerix B® only:**<br>• 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. |
| **Very rapid (super accelerated) schedule of Engerix B® only:**<br>• 3 doses at 0, 7 days and 21 days<br>• further dose 12 months after the first dose is recommended to be considered protected | 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. |
| **Booster (Engerix B®, HBvaxPro®)***:<br>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:<br>• at the time of a subsequent significant exposure - see Table 18.7 on page 17 The 'Green Book' Chapter 18 (covered by this PGD)<br>• individuals with renal failure (see Hep B renal PGD) | |

*HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.

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

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

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| **Quantity to be supplied / 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/wholesalers.<br>Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see protocol for ordering storage and handling of vaccines and 'The Green Book' Chapter 3). |
| **Storage** | Store at between +2°C to +8°C.<br>Store in original packaging in order to protect from light.<br>Do not freeze.<br>In the event of an unavoidable temperature excursion 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.<br>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.<br>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to PHE Vaccine Incident Guidance or any subsequent UKHSA update. |
| **Disposal** | Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.<br>May be given at the same time as other vaccines.<br>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk |
| **Identification & management of adverse reactions**<br><br>Continued over page<br>**Identification & management of adverse reactions** (continued) | Local reactions following vaccination are very common such as pain, swelling or redness at the injection site, induration.<br>Low grade fever, fatigue, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after HepB vaccination.<br>Hypersensitivity reactions and anaphylaxis can occur but are very rare.<br>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk |

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| **Reporting procedure of adverse reactions** | As with all vaccines, healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.<br><br>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 patient or carer** | Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.<br><br>Immunisation promotional material may be provided as appropriate:<br>• A guide to immunisations up to one year of age<br>• Hepatitis B: what does my positive screening result mean?<br>Available from: www.gov.uk/government/collections/immunisation |
| **Patient advice / follow up treatment** | Inform the individual/carer of possible side effects and their management.<br><br>Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.<br><br>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.<br><br>When administration is postponed advise the individual/carer when to return for vaccination.<br><br>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.<br><br>Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation. Hepatitis B infected mothers 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 at age 12 months to identify if they have become chronically infected with hepatitis B.<br><br>(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 / additional information**<br><br>Continued over page<br>**Special considerations / additional information** (continued) | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.<br><br>**Limitations of HepB vaccination**<br>Because of the long incubation period of hepatitis B, it is possible for unrecognised infection to be present at the time of immunisation. The vaccine may not prevent hepatitis B infection in such cases. The vaccine will not prevent infection caused by other pathogens known to infect the liver such as hepatitis A, hepatitis C and hepatitis E viruses.<br><br>As with any vaccine, a protective immune response may not be elicited in all vaccinees (see Chapter 18 for more detail).<br><br>**Testing for evidence of infection or immunity**<br>Where testing for markers of current or past infection is clinically indicated (such as for sexual and household contacts of hepatitis B |

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| Continued over page<br>**Special considerations / additional information**<br>(continued) | 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.<br><br>Testing children born to hepatitis B infected mothers for HBsAg at 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. This testing can be carried out at the same time as the 12 month vaccine dose is given.<br><br>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 from 12 months of age is particularly important.<br><br>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.<br><br>**Post-exposure prophylaxis**<br>A summary of guidance is given in 'The Green Book' Chapter 18 Table 18.7 on page 17.<br><br>**Hepatitis B immunoglobulin (HBIG)**<br>This PGD does not cover the administration of HBIG.<br><br>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 (see 'The Green Book' Chapter 18 Table 18.7 page 17 for more information).<br><br>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.<br><br>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.<br><br>All babies born to highly infectious mothers (see Table 18.5 page 14 in Chapter 18 of 'The Green Book') and babies of a birthweight of 1500g or less born to any mother infected with hepatitis B, should receive HBIG as well as active immunisation. HBIG may be given simultaneously with vaccine but at a different site.<br><br>**Choice of HepB vaccine**<br>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 infected mothers receiving post-exposure prophylaxis (PEP), followed by other lower risk indications for PEP. Vaccine administration should never be delayed for infants born to |

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| | hepatitis B infected mothers, 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:<br><br>1. Hepatitis B paediatric monovalent vaccine (Engerix B® 10 microgram in 0.5ml or HBvaxPRO® 5 micrograms in 0.5ml)<br>2. Hepatitis B adult monovalent vaccine (Engerix B® 20 micrograms in 1.0ml and HBvaxPRO® 10 micrograms in 1.0ml).<br>3. Combined hepatitis A and B vaccine (see the UKHSA HepA/B PGD).<br><br>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 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.<br><br>**Pregnant women/breast-feeding**<br>There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated vaccines. Since HepB is an inactivated vaccine, the risks to the fetus are negligible and it should be given where there is a definite risk of infection.<br><br>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**<br><br>Continued over page<br>**Records**<br>(continued) | Record:<br>• 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<br>• 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)<br>• name of immuniser<br>• name and brand of vaccine<br>• date of administration<br>• dose, form and route of administration of vaccine<br>• quantity administered<br>• batch number and expiry date<br>• anatomical site of vaccination<br>• advice given, including advice given if excluded or declines immunisation<br>• details of any adverse drug reactions and actions taken<br>• supplied via Patient Group Direction (PGD)<br><br>Records should be signed and dated (or a password controlled immunisers record on e-records).<br><br>All records should be clear, legible and contemporaneous.<br><br>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. |

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| | When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Service (CHIS) using the appropriate documentation/pathway as required by any local or contractual arrangement.<br><br>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

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| **Key references** | **HepB vaccine**<br>• Immunisation Against Infectious Disease: The Green Book Chapter 4, last updated June 2012, Chapter 18, last updated June 2017. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book<br>• Summary of Product Characteristic for Engerix B®, GlaxoSmithKline. 3 November 2020 http://www.medicines.org.uk/emc/medicine/9283<br>• Summary of Product Characteristic for HBvaxPRO® 5mcg and 10mcg. MSD Ltd. 1 January 2021 http://www.medicines.org.uk/emc/medicine/9850 http://www.medicines.org.uk/emc/medicine/9847<br>• 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<br>• 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<br>• Hepatitis B: clinical and public health management https://www.gov.uk/guidance/hepatitis-b-clinical-and-public-health-management<br>**General**<br>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/<br>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners<br>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2<br>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources<br>• UKHSA Immunisation Collection https://www.gov.uk/government/collections/immunisation<br>• PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors<br>• Protocol for ordering storage and handling of vaccines. April 2014. https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines |

## 7. Practitioner authorisation sheet

**HepB PGD v04.00 Valid from: 01 November 2021 Expiry: 31 October 2023**

Before signing this PGD, check that the document has had the necessary authorisations in section two. 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 |
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### Authorising manager

| I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **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 A

**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 |
| *20 micrograms of Engerix B® may be given to children 11-15 years of age if using the two dose schedule.<br>**During supply shortages of paediatric hepatitis B containing vaccine, the full 1ml adult preparation of hepatitis B containing vaccine may be administered to infants (off-label) rather than delay or risk omitting HepB vaccination in individuals at high risk (see Additional Information). The adult preparations may be used interchangeably with the paediatric products when vaccine becomes available (see Additional Information for order of preference). | | | |

**Table 2: Pre- and post-exposure prophylaxis schedules for Engerix B® or HBvaxPRO®**

| Schedule | Examples of when to use this schedule |
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| **Usual pre- and post-exposure prophylaxis accelerated schedule*:**<br>• 3 doses at 0, 1, and 2 months<br>• further dose 12 months after the first dose for babies born to hepatitis B infected mothers and individuals at continued high risk | Used for individuals of all ages for pre- and post-exposure prophylaxis.<br>This is the preferred schedule for babies born to hepatitis B infected mothers. 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. |
| **Alternative schedule*:**<br>• 3 doses at 0, 1, and 6 months | This is rarely the most appropriate schedule. It should only be used when rapid protection is not required and there is a high likelihood of compliance with the regimen. |
| **Two dose schedule of Engerix B® only:**<br>• 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. |
| **Very rapid (super-accelerated) schedule of Engerix B® only:**<br>• 3 doses at 0, 7 days and 21 days<br>• further dose 12 months after the first dose is recommended to be considered protected | 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 |
| **Booster (Engerix B®, HBvaxPro®)*:**<br>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:<br>• at the time of a subsequent significant exposure - see Table 18.7 page 17 The 'Green Book' Chapter 18 (covered by this PGD)<br>• individuals with renal failure (see Hep B renal PGD) | |

*HBvaxPRO® and Engerix B® may be used interchangeably to complete the vaccine course.

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