



PHE publications gateway number: GW-302

## PATIENT GROUP DIRECTION (PGD)

Administration of Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed) to individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure that is likely to require haemodialysis or transplant.

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 Renal PGD  
Version no: v02.00  
Valid from: 01 May 2019  
Review date: 01 November 2020  
Expiry date: 30 April 2021

**Public Health England has developed this PGD to facilitate the delivery of publicly funded immunisation 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 product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **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.

**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 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](mailto:immunisation@phe.gov.uk)




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

## Change history

| Version number | Change details   | Date       |
|----------------|--|------------|
| V01.00         | New PHE PGD template   | 28/03/2017 |
| V02.00         | HepB Renal PGD amended to: <ul style="list-style-type: none"><li>• include additional healthcare practitioners in Section 3</li><li>• include HBvaxPRO<sup>®</sup> temperature excursion stability</li><li>• refer to vaccine incident guidelines in off-label and storage sections</li><li>• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGDs</li></ul> | 12/03/2019 |

## 1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

| Developed by:                                      | Name   | Signature  | Date       |
|--|--|--|------------|
| <b>Pharmacist</b><br>(Lead Author)                 | Elizabeth Graham<br>Lead Pharmacist - Immunisation and Countermeasures, PHE                |  | 20/03/2019 |
| <b>Doctor</b>                                      | Mary Ramsay<br>Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE |  | 15/03/2019 |
| <b>Registered Nurse</b><br>(Chair of Expert Panel) | David Green<br>Nurse Consultant – Immunisation and Countermeasures, PHE                    |  | 14/03/2019 |

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Management Group and the PHE Quality and Clinical Governance Delivery Board.

### Expert Panel

| Name                | Designation   |
|---------------------|---|
| Ed Gardner          | Advanced Paramedic Practitioner / Emergency Care Practitioner, Medicines Manager, Proactive Care Lead                           |
| Michelle Jones      | Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG                                |
| Jacqueline Lamberty | Lead Pharmacist Medicines Management Services, Public Health England  |
| Vanessa MacGregor   | Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team                         |
| Alison Mackenzie    | Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England / NHS England South (South West)   |
| Sema Mandal         | Medical Consultant Epidemiologist, Public Health England  |
| Gill Marsh          | Senior Screening and Immunisation Manager Public Health England / NHS England Lancashire and South Cumbria                      |
| Lesley McFarlane    | Screening and Immunisation Co-ordinator , NHS England / Public Health England Leicestershire, Lincolnshire and Northamptonshire |
| Sally Millership    | Consultant in Communicable Disease Control, Public Health England, East of England Health Protection Team                       |
| Tushar Shah         | Pharmacy Advisor, NHS England London Region   |
| Sharon Webb         | Programme Manager / Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England         |


## 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 Cumbria and North East** 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 providing immunisation services.                          |
| Limitations to authorisation   |
| Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East (NHS England North) |

| Organisational approval (legal requirement)  |                 |  |            |
|--|-----------------|--|------------|
| Role   | Name            | Sign   | Date       |
| Assistant Medical Director and Responsible Officer, NHS England Cumbria and North East | Dr James Gossow |  | 29/04/2019 |

| Additional signatories according to locally agreed policy |      |      |      |
|---|------|------|------|
| Role  | Name | Sign | Date |
|   |      |      |      |
|   |      |      |      |
|   |      |      |      |
|   |      |      |      |

Local enquiries regarding the use of this PGD may be directed to:

NHS England Screening and Immunisation Team: Telephone 011382 53017/ Email - [england.cane.screeningimms@nhs.net](mailto:england.cane.screeningimms@nhs.net)) or NECS Medicines Optimisation Pharmacists Sue White or Hira Singh (Tel: 0191 217 2533 / 01642 746875; emails: [sue.white14@nhs.net](mailto:sue.white14@nhs.net) or [hira.singh@nhs.net](mailto:hira.singh@nhs.net) respectively.

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

|  |  |
|--|--|
| <p><b>Qualifications and professional registration</b></p> | <p>Registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> <li>• nurses and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>• pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services)</li> <li>• paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC)</li> </ul> <p>The practitioners above must also fulfil the <a href="#">Additional requirements</a> detailed below.</p> <p>Check <a href="#">Section 2 Limitations to authorisation</a> to confirm whether all practitioners listed above have organisational authorisation to work under this PGD.</p>   |
| <p><b>Additional requirements</b></p>                      | <p>Additionally practitioners:</p> <ul style="list-style-type: none"> <li>• must be authorised by name as an approved practitioner under the current terms of this PGD before working to it</li> <li>• must have undertaken appropriate training for working under PGDs for supply/administration of medicines</li> <li>• must be competent in the use of PGDs (see <a href="#">NICE Competency framework</a> for health professionals using PGDs)</li> <li>• must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('<a href="#">The Green Book</a>'), and national and local immunisation programmes</li> <li>• must have undertaken training appropriate to this PGD as required by local policy and in line with the <a href="#">National Minimum Standards and Core Curriculum for Immunisation Training</a></li> <li>• must be competent to undertake immunisation and to discuss issues related to immunisation</li> <li>• must be competent in the handling and storage of vaccines, and management of the 'cold chain'</li> <li>• must be competent in the recognition and management of anaphylaxis</li> <li>• must have access to the PGD and associated online resources</li> <li>• should fulfil any additional requirements defined by local policy</li> </ul> <p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p> |
| <p><b>Continued training requirements</b></p>              | <p>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).</p> <p>Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and other sources of medicines information.</p> <p>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.</p>  |

#### 4. Clinical condition or situation to which this PGD applies

|   |   |
|---|---|
| <p><b>Clinical condition or situation to which this PGD applies</b></p>   | <p>Indicated for the active immunisation of individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant in accordance with the recommendations given in <a href="#">Chapter 7</a> and <a href="#">Chapter 18</a> of Immunisation Against Infectious Disease: 'The Green Book'.</p>   |
| <p><b>Criteria for inclusion</b></p>  | <p>Individuals who are 15 years of age or over and are on haemodialysis, a renal transplantation programme or have chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant.</p>  |
| <p><b>Criteria for exclusion<sup>2</sup></b></p>  | <p>Individuals for whom no valid consent has been received.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are under 15 years of age</li> <li>• have had a confirmed anaphylactic reaction to a previous dose of hepatitis B containing vaccine or to any components of the vaccine</li> <li>• are known to have markers of current (HBsAg) or past (anti-HBcore) hepatitis B infection</li> <li>• do not have a renal indication for HepB vaccination (see PHE HepB PGD)</li> <li>• are suffering from acute severe febrile illness (the presence of a minor illness without fever or systemic upset is not a contraindication for immunisation)</li> </ul>  |
| <p><b>Cautions including any relevant action to be taken</b></p>  | <p>Syncope (fainting) can occur following, or even before any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>Use caution when vaccinating individuals with severe (ie anaphylactic) allergy to latex. The HBvaxPRO<sup>®</sup> syringe plunger, stopper and tip cap contain dry natural latex rubber; use an alternative vaccine if available.</p> <p>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.</p> |
| <p><b>Action to be taken if the patient is excluded</b></p> <p>continued over page<br/><b>Action to be taken if the</b></p> | <p>Individuals who are under 15 years of age who are on haemodialysis, or renal transplantation programmes, or with chronic renal failure (CKD stage 4 or 5) that is likely to require haemodialysis or transplant, should be referred for specialist advice on the appropriate vaccination schedule. A PSD is required as vaccination of these individuals is outside the remit of this PGD.</p> <p>Individuals who have had a confirmed anaphylactic reaction to a previous dose of HepB vaccine or any components of the vaccine</p>   |

<sup>2</sup> 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

|   |  |
|---|--|
| <p><b>patient is excluded</b><br/>(continued)</p>                           | <p>should be referred to a clinician for specialist advice and appropriate management.</p> <p>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.</p> <p>Individuals who do not have a renal indication for HepB vaccination should be managed in accordance with PHE HepB PGD.</p> <p>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.</p> <p>Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required.</p> <p>The risk to the individual of not being immunised must be taken into account.</p> <p>Document the reason for exclusion and any action taken in the individual's clinical records.</p> <p>In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.</p> |
| <p><b>Action to be taken if the patient or carer declines treatment</b></p> | <p>Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration.</p> <p>Advise the individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications.</p> <p>Document advice given and the decision reached.</p> <p>In a GP practice setting, inform or refer to the GP as appropriate.</p>  |
| <p><b>Arrangements for referral for medical advice</b></p>                  | <p>As per local policy</p>   |

## 5. Description of treatment

|  |  |
|--|--|
| <b>Name, strength &amp; formulation of drug</b>  | <p>Hepatitis B recombinant DNA (rDNA) vaccine (adsorbed)* (HepB) eg:</p> <ul style="list-style-type: none"> <li>• Engerix B<sup>®</sup> 20micrograms/1ml suspension for injection in pre-filled syringe or vial</li> <li>• Fendrix<sup>®</sup> 20 micrograms/0.5ml suspension for injection in pre-filled syringe*</li> <li>• HBvaxPRO<sup>®</sup> 40micrograms/1ml suspension for injection in a vial</li> </ul> <p>*the hepatitis B surface antigen in Fendrix<sup>®</sup> is adjuvanted by AS04C</p>  |
| <b>Legal category</b>  | <p>Prescription only medicine (POM)</p>  |
| <b>Black triangle▼</b>   | <p>No</p>  |
| <b>Off-label use</b>   | <p>Administration of Fendrix<sup>®</sup> by deep subcutaneous injection to patients with a bleeding disorder is off-label administration in line with advice in <a href="#">Chapter 4</a> and <a href="#">Chapter 18</a> of “The Green Book”.</p> <p>Recommendations in the Green Book <a href="#">Chapter 18</a> allow for concomitant administration of HepB vaccine with other vaccines at a separate site when required. For Fendrix<sup>®</sup>, such administration would be off-label as, due to a lack of data, the SPC for Fendrix<sup>®</sup> advises an interval of 2 to 3 weeks be respected between the administration of Fendrix<sup>®</sup> and other vaccines.</p> <p>Vaccine should be stored according to the conditions detailed in the <a href="#">Storage section</a> below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to <a href="#">PHE Vaccine Incident Guidance</a>. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/patient/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.</p> |
| <b>Route / method of administration</b><br><br>Continued over page<br><b>Route / method of</b> | <p>Administer by intramuscular injection into the deltoid region of the upper arm. The buttock should not be used because vaccine efficacy may be reduced.</p> <p>When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each was given should be noted in the individual's records.</p> <p>For individuals with a bleeding disorder, vaccines normally given by an intramuscular route should be given by deep subcutaneous injection to reduce the risk of bleeding (see ‘The Green Book’ <a href="#">Chapter 4</a>).</p> <p>The vaccine may settle during storage, shake the vaccine well before administration to obtain a slightly opaque (HBvaxPro<sup>®</sup>) or turbid (Fendrix<sup>®</sup>/ Engerix B<sup>®</sup>), white suspension.</p> <p>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,</p>   |



| <b>administration</b><br>(continued)  | do not administer the vaccine.<br>The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
|---|---|-------------------|-----------|------|--------|--|------------------------|-------------------|-----------|--|-----------------------|---------------|-------|--|----------------------|---------------|-------|----------|---------------------------------------|---|---|--|---|---|---|---|---|
| <b>Dose and frequency of administration</b>   | <p>Current UK licensed HepB vaccines contain different concentrations of antigen per millilitre.</p> <p><b>Table 1: Current UK licensed HepB vaccine doses for adolescents and adults with renal insufficiency including dialysis</b></p> <table border="1" data-bbox="549 479 1447 887"> <thead> <tr> <th>Age</th> <th>Vaccine</th> <th>Dose</th> <th>Volume</th> </tr> </thead> <tbody> <tr> <td>Patients with renal insufficiency and dialysis patients aged 16 years and over</td> <td>Engerix B<sup>®</sup></td> <td>2 x 20 micrograms</td> <td>2 x 1.0ml</td> </tr> <tr> <td>Adult dialysis and pre-dialysis patients</td> <td>HBvaxPRO<sup>®</sup></td> <td>40 micrograms</td> <td>1.0ml</td> </tr> <tr> <td>Patients with renal insufficiency aged 15 years and over</td> <td>Fendrix<sup>®</sup></td> <td>20 micrograms</td> <td>0.5ml</td> </tr> </tbody> </table> <p><b>Table 2: Schedule for adolescents and adults with renal insufficiency including dialysis</b></p> <table border="1" data-bbox="549 994 1447 1933"> <thead> <tr> <th>Schedule</th> <th>Examples of when to use this schedule</th> </tr> </thead> <tbody> <tr> <td> <b>Engerix B<sup>®</sup> 20micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>4 double doses (2 x 20 micrograms) at 0,1, 2 and 6 months after the first dose</li> </ul> </td> <td>Use for individuals from 16 years of age.</td> </tr> <tr> <td> <b>HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>3 doses at 0,1 and 6 months after the first dose</li> </ul> </td> <td>Use for individuals from 16 years of age.</td> </tr> <tr> <td> <b>Fendrix<sup>®</sup>:</b> <ul style="list-style-type: none"> <li>4 doses at 0,1, 2 and 6 months after the first dose</li> </ul> </td> <td>Use for individuals from 15 years of age.</td> </tr> <tr> <td> <b>Booster (Engerix B<sup>®</sup> 20micrograms / 1.0ml, HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml or Fendrix<sup>®</sup>):</b> <ul style="list-style-type: none"> <li>single dose administered if anti-HBs levels fall below 10mIU/ml in an individual who has previously responded to the vaccine (levels should be monitored annually)</li> <li>single dose to haemodialysis patients travelling to highly endemic areas if they have not received a booster in the last 12 months</li> </ul> </td> <td>Individuals on haemodialysis from 15 years of age (Engerix B<sup>®</sup> or HBvaxPRO<sup>®</sup> from 16 years of age or Fendrix<sup>®</sup> from 15 years of age)</td> </tr> </tbody> </table> <p>Where immunisation has been delayed beyond the recommended intervals, the vaccine course should be resumed but not repeated.</p> | Age               | Vaccine   | Dose | Volume | Patients with renal insufficiency and dialysis patients aged 16 years and over | Engerix B <sup>®</sup> | 2 x 20 micrograms | 2 x 1.0ml | Adult dialysis and pre-dialysis patients | HBvaxPRO <sup>®</sup> | 40 micrograms | 1.0ml | Patients with renal insufficiency aged 15 years and over | Fendrix <sup>®</sup> | 20 micrograms | 0.5ml | Schedule | Examples of when to use this schedule | <b>Engerix B<sup>®</sup> 20micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>4 double doses (2 x 20 micrograms) at 0,1, 2 and 6 months after the first dose</li> </ul> | Use for individuals from 16 years of age. | <b>HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>3 doses at 0,1 and 6 months after the first dose</li> </ul> | Use for individuals from 16 years of age. | <b>Fendrix<sup>®</sup>:</b> <ul style="list-style-type: none"> <li>4 doses at 0,1, 2 and 6 months after the first dose</li> </ul> | Use for individuals from 15 years of age. | <b>Booster (Engerix B<sup>®</sup> 20micrograms / 1.0ml, HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml or Fendrix<sup>®</sup>):</b> <ul style="list-style-type: none"> <li>single dose administered if anti-HBs levels fall below 10mIU/ml in an individual who has previously responded to the vaccine (levels should be monitored annually)</li> <li>single dose to haemodialysis patients travelling to highly endemic areas if they have not received a booster in the last 12 months</li> </ul> | Individuals on haemodialysis from 15 years of age (Engerix B <sup>®</sup> or HBvaxPRO <sup>®</sup> from 16 years of age or Fendrix <sup>®</sup> from 15 years of age) |
| Age   | Vaccine   | Dose              | Volume    |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| Patients with renal insufficiency and dialysis patients aged 16 years and over  | Engerix B <sup>®</sup>  | 2 x 20 micrograms | 2 x 1.0ml |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| Adult dialysis and pre-dialysis patients  | HBvaxPRO <sup>®</sup>   | 40 micrograms     | 1.0ml     |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| Patients with renal insufficiency aged 15 years and over  | Fendrix <sup>®</sup>  | 20 micrograms     | 0.5ml     |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| Schedule  | Examples of when to use this schedule   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| <b>Engerix B<sup>®</sup> 20micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>4 double doses (2 x 20 micrograms) at 0,1, 2 and 6 months after the first dose</li> </ul>   | Use for individuals from 16 years of age.   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| <b>HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml:</b> <ul style="list-style-type: none"> <li>3 doses at 0,1 and 6 months after the first dose</li> </ul>  | Use for individuals from 16 years of age.   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| <b>Fendrix<sup>®</sup>:</b> <ul style="list-style-type: none"> <li>4 doses at 0,1, 2 and 6 months after the first dose</li> </ul>   | Use for individuals from 15 years of age.   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| <b>Booster (Engerix B<sup>®</sup> 20micrograms / 1.0ml, HBvaxPRO<sup>®</sup> 40micrograms / 1.0ml or Fendrix<sup>®</sup>):</b> <ul style="list-style-type: none"> <li>single dose administered if anti-HBs levels fall below 10mIU/ml in an individual who has previously responded to the vaccine (levels should be monitored annually)</li> <li>single dose to haemodialysis patients travelling to highly endemic areas if they have not received a booster in the last 12 months</li> </ul> | Individuals on haemodialysis from 15 years of age (Engerix B <sup>®</sup> or HBvaxPRO <sup>®</sup> from 16 years of age or Fendrix <sup>®</sup> from 15 years of age)   |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |
| <b>Duration of treatment</b>  | Dependent on vaccine schedule, see <a href="#">Dose and frequency of</a>  |                   |           |      |        |  |                        |                   |           |  |                       |               |       |  |                      |               |       |          |                                       |   |   |  |   |   |   |   |   |

|   |   |
|---|---|
|   | <a href="#">administration.</a>   |
| <b>Quantity to be supplied / administered</b>               | Dose of 0.5ml to 2ml per an administration depending on the vaccine product used, see <a href="#">Dose and frequency of administration.</a>   |
| <b>Supplies</b>   | 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 <a href="#">protocol for ordering storage and handling of vaccines</a> and Green Book <a href="#">Chapter 3</a> ).   |
| <b>Storage</b>  | Store at between +2°C to +8°C.<br>Store in original packaging in order to protect from light.<br>Do not freeze.<br><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><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 <a href="#">PHE Vaccine Incident Guidance.</a> |
| <b>Disposal</b>   | 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 regulations and guidance in the <a href="#">technical memorandum 07-01: Safe management of healthcare waste</a> (Department of Health, 2013).   |
| <b>Drug interactions</b>                                    | Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited.<br><br>May be given at the same time as other vaccines.<br><br>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>  |
| <b>Identification &amp; management of adverse reactions</b> | Local reactions following vaccination are very common ie pain, swelling or redness at the injection site, induration.<br><br>Low grade fever, fatigue, drowsiness, headache, irritability, appetite loss and gastrointestinal symptoms (nausea, vomiting, diarrhoea, and abdominal pain) have been commonly reported symptoms after HepB vaccination.<br><br>Hypersensitivity reactions and anaphylaxis can occur but are very rare.<br><br>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>   |

|   |   |
|---|---|
| <p><b>Reporting procedure of adverse reactions</b></p>            | <p>Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed.</p>  |
| <p><b>Written information to be given to patient or carer</b></p> | <p>Offer marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine.</p>  |
| <p><b>Patient advice / follow up treatment</b></p>                | <p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p> <p>When administration is postponed advise the individual/carer when to return for vaccination.</p> <p>Individuals/carers should be informed about the importance of completing a course of hepatitis B immunisation.</p>   |
| <p><b>Special considerations / additional information</b></p>     | <p>Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination.</p> <p><b>Limitations of HepB vaccination</b></p> <p>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.</p> <p>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.</p> <p>As with any vaccine, a protective immune response may not be elicited in all vaccinees (see <a href="#">Chapter 18</a> for more detail).</p> <p><b>Testing for evidence of infection or immunity</b></p> <p>Additional vaccine doses may need to be considered for persons who do not respond or have a sub-optimal response to a course of vaccinations. Refer to <a href="#">Chapter 18</a> for advice on response to vaccine and the use of additional doses.</p> <p><b>Choice of HepB vaccine</b></p> <p>The response to HepB vaccine among patients with renal failure is lower than among healthy adults. However, increased response rates have been reported in vaccines formulated for use in patients with chronic renal failure. Therefore, the vaccines formulated for use in patients with chronic renal insufficiency should be used for these individuals.</p> <p><b>Pregnant women/breastfeeding</b></p> <p>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 foetus are negligible and it should be given where there is a definite risk of infection.</p> |

|                       |   |
|-----------------------|---|
| <p><b>Records</b></p> | <p>Record:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given</li> <li>• name of individual, address, date of birth and GP with whom the individual is registered</li> <li>• name of immuniser</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if excluded or declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled immunisers record on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>The local Child Health Information Services team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> |
|-----------------------|---|

## 6. Key references

|                       |  |
|-----------------------|--|
| <b>Key references</b> | <p><b>HepB vaccine</b></p> <ul style="list-style-type: none"><li>• Immunisation Against Infectious Disease: The Green Book <a href="#">Chapter 4</a>, last updated June 2012, <a href="#">Chapter 18</a>, last updated 17 July 2017. <a href="https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book">https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</a></li><li>• Summary of Product Characteristic for Engerix B<sup>®</sup>, GlaxoSmithKline. 24 April 2017. <a href="http://www.medicines.org.uk/emc/medicine/9283">http://www.medicines.org.uk/emc/medicine/9283</a><br/><a href="http://www.medicines.org.uk/emc/medicine/24844">http://www.medicines.org.uk/emc/medicine/24844</a></li><li>• Summary of Product Characteristic for HBvaxPRO<sup>®</sup> 40mcg. MSD Ltd. 12 March 2019. <a href="http://www.medicines.org.uk/emc/medicine/9848">http://www.medicines.org.uk/emc/medicine/9848</a></li><li>• Summary of Product Characteristic for Fendrix<sup>®</sup>. GlaxoSmithKline. 2 November 2018. <a href="http://www.medicines.org.uk/emc/medicine/16906">http://www.medicines.org.uk/emc/medicine/16906</a></li></ul> <p><b>General</b></p> <ul style="list-style-type: none"><li>• Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <a href="https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste">https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste</a></li><li>• National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <a href="https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners">https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners</a></li><li>• NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <a href="https://www.nice.org.uk/guidance/mpg2/resources">https://www.nice.org.uk/guidance/mpg2/resources</a></li><li>• PHE Immunisation Collection <a href="https://www.gov.uk/government/collections/immunisation">https://www.gov.uk/government/collections/immunisation</a></li><li>• PHE Vaccine Incident Guidance <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li><li>• Protocol for ordering storage and handling of vaccines. April 2014. <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a></li></ul> |
|-----------------------|--|

## 7. Practitioner authorisation sheet

**HepB Renal PGD v02.00 Valid from: 01/05/2019 Expiry: 30/04/2021**

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 |
|------|-------------|-----------|------|
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |

### 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.