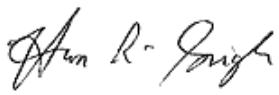
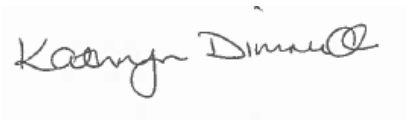
Patient Group Direction (PGD) for the Administration of

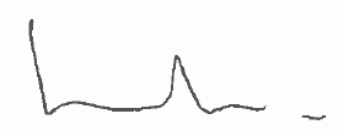
HEPATITIS B VACCINES

by Registered Professionals to Individuals Accessing NHS Services in Cumbria and North East Sub Region (NHS England North)

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT.

Direction Number: - **NECSAT 2017/002**
Valid from: 1st March 2017
Review date: 1st December 2018
Expiry date: 31st March 2019

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		21/02/17
Transforming Care Quality Manager (NHS England, Cumbria and North East)	**Kathryn Dimmick** *(Senior Nurse)*		21/02/17
Medicines Optimisation Pharmacist (North of England Commissioning Support)	**Marie Thompkins** *(Senior Pharmacist)*		22/02/17
Assistant Medical Director (NHS England, Cumbria and North East)	**Dr James Gossow** *(Senior Doctor)*		27/02/17

This PGD has been approved for use in Cumbria and North East Sub Region (NHS England) by:			
Title	Name	Signature	Date
Interim Medical Director (NHS England Cumbria and North East)	**Dr Jonathan Slade** *(Governance Authorisation)*		28/02/17

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

Patients identified to be at risk of Hepatitis B (Refer to Chapter 18 v3_0, Green Book (Feb.2016) online version

Objectives of care

- To prevent infectious disease and promote health. To reduce morbidity & mortality and to eradicate disease.

Inclusion criteria (as per Public Health England (PHE) Green Book Guidance

(Only use those criteria that are specific to your authorised role & competence).

Those at increased risk of contracting Hepatitis B and where valid consent has been given/ best interest decision is in place. These include: -

- Individuals receiving regular blood or blood products (e.g. Haemophiliacs) & carers responsible for the administration of such products;
- Those in residential accommodation with learning difficulties;
- Adults and children in day care, schools and centres for those with severe learning disability;
- Close family contacts of a case or individual with chronic hepatitis B infection;
- Families adopting children from countries with a high/intermediate prevalence of hepatitis B;
- Short-term foster carers (and their families) receiving emergency foster placements;
- Permanent foster carers (& their families) adopting/fostering children known to be at high risk of Hepatitis B;
- Individuals who change sexual partners frequently;
- Men who have sex with men;
- Male and female commercial sex workers;
- Injecting drug users (including those who inject intermittently);
- Sexual partners of injecting users;
- Those likely to "progress" to injecting, (e.g. currently smoking heroin);
- Children of injectors;
- Non-injecting user living with current injector;
- Inmates of custodial institutions;
- Those requesting the vaccine for occupational health risk;
- Those with chronic liver disease & chronic renal failure (See also the Additional Information section);
- Travellers to areas of high or intermediate prevalence where there may be exposure to risk of infection and who are at increased risk, or who intend to remain for lengthy periods. (See Green Book, chapter 18, page 171 for additional details).

- ***Refer to chapter 18 of the current "Green Book" for full details of inclusion.***
- ***Please also refer Hepatitis B for Infants PGD (NECSAT 2016/018)***
- *Additional vaccine related advice may also be obtained from Nathnac (http://nathnac.net/) and Travax (http://www.travax.nhs.uk) websites.*

Exclusion criteria

General exclusions *(Refer to current Summary of Product Characteristics (SPC) &/or BNF for full list of details)***: -**

- No valid consent or best interest decision is in place;
- Patient is acutely unwell (postpone vaccination until recovered. Minor infections without fever or systemic upset are not reasons to postpone immunisation).
- Confirmed anaphylactic reaction to any component, excipient or trace residue of the vaccine. Practitioners must check the SPC.
- Confirmed anaphylactic reaction to a previous dose of Hepatitis B containing vaccines.
- Severe hypersensitivity to any ingredient or component of the vaccine(s) – **(please also refer to precautions section).**
- Any child who had apnoea, bradycardia or desaturations after the first immunisation – (Refer into hospital)

Precautions

- Hypersensitivity reactions to previous dose of vaccine or component of vaccine:
  - **NB**. "Local adverse reactions that generally start within a few hours of the injection are usually mild and self-limiting. Although these are often referred to as 'hypersensitivity reactions', they are not allergic in origin, but may be either due to high titres of antibody or a direct effect of the vaccine product, e.g. endotoxin in whole-cell bacterial vaccines. The occurrence or severity of such local reactions does not contraindicate further doses of immunisation with the same vaccine or vaccines containing the same antigens."
- Immediate access to epinephrine (adrenaline) 1 in 1000 injection. Syringes and needles of suitable size and capacity for dose should be available.
- **When two or more injections need to be administered at the same time**, they should be given at separate sites, preferably in a different limb. If more than one injection is to be given in the same limb they should be administered at least 2.5cm apart.

Action if excluded

- Discuss with or refer to clinician/doctor. Ensure all actions/decisions are documented.
- The risk to the individual of not being immunised must be taken into account.
- If postponement due to acute illness, arrange a future date for immunisation.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Patient meeting the exclusion criteria
- Patient requires additional information in order to decide whether or not to have the vaccination
- A Best Interest decision is required for an individual who lacks mental capacity to consent. Seek support from lead clinician responsible for individuals care.

Action if vaccination refused

- Refusal should be accepted. Ensure patient/guardian/carer fully understands the risks of declining vaccination.
- Advise about protective effects of vaccine & the risks of infection and disease complications If postponement due to acute illness, arrange a future date for immunisation
- Document refusal, advice given, actions/decisions in notes (written or electronic). Inform or refer to doctor as appropriate

Special Considerations / Additional Information

- Protection against hepatitis B starts to develop within 1 month.
- Patients receiving immunosuppressive treatments or with immunodeficiency, an adequate response may not be achieved.
- Patients with chronic renal failure, haemodialysis patients and HIV positive subjects, additional doses of vaccine may be needed to ensure a protective anti-HB's level ≥ 10IU/l. Therefore, antibody levels should be monitored at least annually.
- If started with Fendrix for primary course of vaccination at 0, 1, 2 and 6 months then should be completed with Fendrix
- Fendrix can be used as booster dose after a primary vaccination course with either Fendrix or any other Hep B vaccine.
- These vaccines can be used to complete a primary immunisation course or as a booster dose in subjects who have previously received another hepatitis B vaccine
- These vaccines can be administered concomitantly with other vaccines, using separate sites and syringes.
- Prior to administration the vaccine should be well shaken to obtain a slightly opaque, white suspension.
- **Pregnancy & Breast feeding**

  - Immunisation should not be withheld from pregnant women in a high risk category or where there is a definite risk of infection; There is no evidence of risk from vaccinating pregnant women or those who are breast feeding with inactivated viral or bacterial vaccines or toxoids.

2. Description of treatment

Name, strength & formulation of drug

Engerix B® 20mcg/1ml Suspension for injection in 0.5ml and 1ml vials (GSK)

- **0.5ml** (10mcg/0.5ml) Vial (type I glass) contains **one 10microgram dose.**
- **1.0ml** (20mcg/1ml) Vial (type 1 glass) contains **one 20microgram dose**.
- Once shaken the vaccine is a slightly opaque white suspension.

Engerix B® 20mcg/1ml Suspension for injection in 0.5ml & 1ml pre-filled syringes (GSK)

- **0.5ml** (10mcg/0.5ml) pre-filled syringe (type I glass) contains **one 10microgram dose.**
- **1.0ml** (20mcg/1ml) pre-filled syringe (type 1 glass) contains **one 20microgram dose**.
- Once shaken the vaccine is a slightly opaque white suspension.

Fendrix®	20mcg/0.5ml	(GSK): -	**0.5ml pre-filled syringe**	(Turbid white suspension)
HBVAXPRO® 5mcg	5mcg/0.5ml	(MSD): -	**0.5ml pre-filled syringe**	(Slightly opaque white suspension)
HBVAXPRO® 10mcg	10mcg/ml	(MSD): -	**1ml pre-filled syringe**	(Slightly opaque white suspension)
HBVAXPRO® 40mcg	40mcg/ml	(MSD): -	**1ml vial**	(Slightly opaque white suspension)

(Please note: Micrograms = mcg = µg)

Legal Status:

POM –Prescription Only Medicines

Dosage /Dose range

Vaccine product	Ages & Group	Dose	Volume
Engerix B® 10µg/0.5ml	0-15 years***** :	10µg	0.5ml
Engerix B® 20µg/1ml	16 years old or over:	20µg	1ml
Fendrix®	Patients with renal Insufficiency ≥ 15yrs old (including pre-haemodialysis and haemodialysis) ***(Fendrix is recommended to be given at 0, 1, 2 and 6months)***	20µg	0.5ml
HBvaxPRO® 5µg	0-15 years:	5µg	0.5ml
HBvaxPRO® 10µg	16 years and over:	10µg	1ml
HBvaxPRO® 40µg	Adult dialysis & pre-dialysis patients (green book p.167)	40µg	1.0ml

***** 20µg of Engerix B may be given to children 11–15 years of age if using the two-dose schedule (see frequency of administration section)

Route/Method

Intramuscular injection (IM) is the preferred route: -

- **Deltoid region in adults, adolescents and children. Anterolateral thigh in infants.**
- **Not** to be given intravenously.
- **Not** to be administered in the gluteal muscle or intradermally since this may result in lower immune response.
- Exceptionally, can be administered subcutaneously in patients with thrombocytopenia or bleeding disorders.

(Please refer to the manufacturer's SPCs and on line version of the Green Book for detailed information).

Frequency of Administration

For pre-exposure prophylaxis in high risk groups and for post exposure prophylaxis (For full details refer to manufacturers SPC and the current Green Book, chapter 18 Hepatitis B (on-line version) **: -**

Primary immunisation (accelerated Schedule)

For pre-exposure prophylaxis in most adults and childhood risk groups, an accelerated schedule should be used.

Where compliance with prolonged schedule is difficult to achieve (e.g. in injecting drug users and GUM clinic attenders).

- 1st dose: - At the elected date. **HBvaxPRO 5mcg & 10mcg vaccines**
- 2nd dose: - 1 month after the 1st dose. **Engerix B**
- 3rd dose: - 2 months after the first dose.
- 4th dose: - at 12 months after 1st dose (recommended **only** for those infants who are at continued risk **or** as an **opportunistic dose** for others)

For post-exposure prophylaxis, - use an accelerated schedule with vaccine given at zero, one and two months (as above).
(For those at continued risk, a fourth dose is recommended at 12 months).
For babies born to mothers infected with hepatitis B – **please refer to PGD (NECSAT 2016/018)**

Primary Schedule

For pre-exposure prophylaxis where rapid protection **is not** required & there is a high likelihood of compliance. Gives optimal protection at 7 months : -

- 1st dose: - At the elected date.
- 2nd dose: - One month after the first dose.
- 3rd dose: - 6 months after the first dose.

HBVAXPRO 5mcg, 10mcg & 40mcg vaccines
Engerix B

Two Dose Schedule (for children aged 11 years to under 15 years of age)

A two-dose schedule (at zero and six months) of the adult strength vaccine (Engerix B 20mcg injection) provides similar protection to three doses of childhood vaccine. To be used only when there is a low risk of Hep B infection during the vaccination course and completion can be assured.

- 1st dose: - At the elected date
- 2nd dose: - 6 months after the 1st dose

Energix B 20mcg

In exceptional circumstances in adults only (≥18yrs old) **

For those at immediate risk & where a more rapid induction of protection is required, a schedule of 4 intramuscular injections given at 0, 7, 21 days & 12 months may be used. This includes: -

- Injecting drug users & inmates of custodial institutions.
- Persons travelling to areas of high endemicity and who commence a course of vaccination against hepatitis B within 30 days prior to departure, but where insufficient time is available to allow the standard 0, 1 and 6 month schedule to be completed.
    - 1st dose: - At the elected date
    - 2nd dose: - 7 days after the first dose
    - 3rd dose: - 21 days after the first dose
    - 4th dose: - 12 months after 1st dose

Engerix B

** This schedule may also be used for teenagers **16-18 year olds,** where it is important to provide rapid protection and to maximise compliance (e.g. injecting drug users and those in prison) - (Un-licensed for this age group **but** Green Book recommended).

NB. Different hepatitis B vaccine products can be used to complete a primary immunisation course or, when indicated, as a booster dose in individuals who have previously received another hepatits B vaccine (please refer to specific SPC).

Maximum dose

As above (refer to "dose/dose range" section)

Follow up treatment

Follow current Green Book chapter 18 (on-line version) recommendations as applicable

Max. number of treatments: - up to 5 doses (depending on schedule and indication).

Booster dose: - 1 single dose at around 5 years after primary course, **once only**, for those at continued risk of infection

3. Further Aspects of Treatment

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - See manufacturers SPC for full details / current Green Book online Chapter 18

Potential Adverse Effects/ Reactions: - Usually transient and only last a few days after vaccination.

Please be aware of Resuscitation Council Guidelines (2010).

Very Common & Common reactions	**All vaccines** • Injection site soreness, pain, erythema & induration (also Injection site swelling with Fendrix). (Local reactions within 48hrs after vaccination and persisting for 1-2 days). **Engerix**: - Drowsiness, headache (more common in children), nausea, vomiting, diarrhoea, abdominal pain, appetite loss, fatigue, fever, malaise, irritability. **Fendrix: -** Headache, GI disorder, fatigue, fever.
Uncommon, rare and very rare	**All vaccines: -** Anaphylactic and allergic reactions. **Engerix and HBVAXPRO: -** Athralgia, dizziness, influenza-like illness, pruritis, rash, urticaria. **Engerix: -** lympadenopathy, parasthesia. **HBVAXPRO: -** fatigue, fever, malaise, headache, nausea/vomiting/diarrhoea, abdominal pain, myalgia. **Fendrix: -** Vertigo, back pain, rigors, hot flushes, asthenia, tendonitis, viral infection, nervousness

This list is not exhaustive. Please also refer to current manufacturers SPC for details of all potential adverse reactions.

Identification and Management of Adverse Reactions

- Patient/ Carer / Guardian requested to report side effects
- Advice on management including anaphylaxis: - Chapter 8 of the Green Book provides detailed advice on managing adverse drug reactions (ADRs) following immunisation, e.g. Analgesia for pain &/or fever; prevention of dehydration; drinking plenty of clear fluids).
- Refer to doctor/specialist as appropriate

Reporting Procedure of Adverse Effects

- Report to doctor if appropriate & document in patient's medical records.
- All adverse reactions due to ▼ vaccines should be reported to the MHRA using the yellow card system.
- For established vaccines only report serious adverse reaction. Please refer to www.mhra.gov.uk/yellowcard and the online Green Book - Chapter 9.

  See manufacturers SPC for details of all potential adverse reactions.

Advice to Patient / Carer (verbal or written)

- Explain protection level expected from vaccine.
- Provide a patient information leaflet and discuss as required.
- Provide advice on & explain potential warnings & side effects and request to report them if they occur.
- Provide advice on management of adverse reactions (see above and manufacturers SPC).
- Explain procedure for dealing with anaphylaxis /severe allergic reactions.
- Explain the "Out of Hours" procedure. Give date of next vaccine if applicable.
- Provide patient with vaccination record card (to include date of next vaccination, completion of course or blood test) if applicable.
- Complete patient-held vaccination record (where applicable)

Arrangements for Referral to Medical Advice

- Doctor/specialist appointment as and when appropriate. Additional vaccine related advice may also be obtained from Nathnac (http://www.nathnac.org) and Travax (http://www.travax.nhs.uk) websites.

Records

In all cases manual records, computerised records and data collection should include: -

- Patient's name and date of birth;
- Reason vaccination required;
- Date of administration;
- Confirmation that consent has been obtained;
- Dose, site and route of injection;
- Brand name, batch number and expiry date of vaccine;
- Whom administered by and signature of vaccinator (if not recorded on computer).
- Confirmation that there are no contraindications; That side effects have been discussed;
- Support literature given (where applicable);
- Signature and printed name and designation (in black ink) for paper records. For computer records, ensure data authentication of practitioner delivering care.
- Any immunisation/vaccine related incident should be reported to Cumbria and North East Sub Region (NHS England North).

Additional Facilities

- Access to updated online Green Book information; the latest SPC and BNF.
- Store in a clinical refrigerator (+2°C to +8°C) within original packaging. Have access to a telephone.
- Stock control & storage of vaccines in accordance with national and local policies / protocols/ guidelines.
- Emergency equipment available including immediate access to Epinephrine (Adrenaline) 1in 1000 injection (as a minimum). (Please refer to PGD for adrenaline as applicable)

References

- NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
- Public Health England: Immunisation Against Infectious Disease - The "Green Book" Chapter 18: Hepatitis B (February 2016). Accessed at https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18 on 16th January, 2017
- Nursing and Midwifery Council (NMC), 2007: Standards for Medicines Management.
- Nursing and Midwifery Council (NMC), 2007: Record Keeping Advice Sheet.
- Nursing and Midwifery Council (NMC), 2008: Code of Professional Conduct: standards of conduct, performance & ethics for nurses and midwives.
- Resuscitation Council (UK), October 2015: Emergency Medical Treatment of anaphylactic reaction by first medical responders and community nurses. www.resus.org.uk/siteindx.htm
- Sanofi Pasteur MSD Ltd; HBVAXPRO® (5, 10, and 40mcg) vaccines - Summary of Product Characteristics (SPC), 05/06/2014 (accessed from Electronic Medicines Compendium on 16/01/17).
- GlaxoSmithKline Ltd; Engerix B®20mcg/1ml vials vaccine – Summary of Product Characteristics (SPC), 24/11/2015 (accessed from Electronic Medicines Compendium on 16/01/17).
- GlaxoSmithKline Ltd; Engerix B®20mcg/1ml suspension for injection PFS vaccine – Summary of Product Characteristics (SPC), 24/11/2015 (accessed from Electronic Medicines Compendium on 16/01/17).
- GlaxoSmithKline Ltd; Fendrix ® vaccine – Summary of Product Characteristics (SPC), 24/11/2014 (accessed from Electronic Medicines Compendium on 16/01/17).
- General Practitioners Committee (GPC)-BMA, (Nov. 2012): Focus on travel immunisations: Guidance to GPs.
- General Practitioners Committee (GPC) - BMA, (August 2012): Focus on hepatitis B immunisations: Guidance to GPs.
- NHS England; Public Health Functions to be exercised by NHS England Service specification No.1 - Neonatal hepatitis B immunisation programme (December 2014).

4. Characteristics of Healthcare Professional Staff

Only those healthcare professionals that have been specifically <u>authorised by their clinical lead/supervisor/manager</u> may use this PGD for the indications defined within it.

Under current legislation, only the following currently registered healthcare professionals may work under Patient Group Directions (PGDs). These professionals may only supply or administer medicines under a PGD as named individuals. These professionals include -

Pharmacists	Nurses	Chiropodists/Podiatrists
Health Visitors	Physiotherapists	Midwives
Dieticians	Optometrists	Registered Orthoptists
Prosthetists and Orthotists	Radiographers	Occupational Therapists
Speech and Language Therapists	Dental Hygienists	Dental Therapists
State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval.		

Qualifications required (professional registration applies to specific professions)

Professionals using this PGD must be currently registered with their relevant professional body, e.g.

- For Nurses: - Nursing & Midwifery Council (NMC)
- For Pharmacists: - General Pharmaceutical Council (GPhC)
- For Allied Health Professionals: - Health Professions Council

Additional requirements (applies to all staff)

- Maintain knowledge of vaccinations; either through a recognised course or through in-house training supported by attendance at vaccination study day(s).
- Meet the HPA National minimum standards in immunisation training 2005 either through training or professional competence ensuring that annual training is offered to all staff
- Have up to date resuscitation skills and anaphylaxis training (and competent to recognise & manage anaphylaxis).
- Competent to undertake immunisations and have a current authorised Adrenaline PGD.
- Will have undertaken training in the role, care and administration of the medicine specified in the PGD.
- Have access to a current BNF and *Immunisation Against Infectious Disease* (Green Book online version).
- Any additional training requirements as deemed necessary by your organisation or authorising body.

Continued training requirements (applies to all staff)

- Annual attendance at an update on resuscitation skills and the management of anaphylaxis within the community/primary care **(mandatory).**
- Maintenance of own level of updating and competence with evidence of continued professional development.
- Annual updates in immunisation **(recommended).**
- Any continued training requirements as deemed necessary by your organisation or the authorising body.

Management & Monitoring of Patient Group Direction NECSAT 2017/002

The Administration of

HEPATITIS B VACCINES

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professional.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by all registered Healthcare Professionals it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD.
- By signing this document, the healthcare professional confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Name of Healthcare Professional:-_____

I have read and understood the Patient Group Direction.

HEPATITIS B VACCINES

I agree to administer Hepatitis B Vaccines only in accordance with this Patient Group Direction (NECSAT 2017/002)

Signature of Healthcare Professional: - _____

Date signed: - _____

State profession: - _____

Authorisation to use this PGD by: -

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Manager/Clinical Lead: - _____

Signature of Manager/Clinical Lead: - _____

Date signed: - _____

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**

Management & Monitoring of Patient Group Direction NECSAT 2017/002

HEPATITIS B VACCINES

Healthcare Professional Authorisation (service/practice list)

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named healthcare professionals.

- This page should be signed by all healthcare professionals authorised to use this PGD and retained and kept on file by the service/practice manager as a record of all practitioners authorised to use this PGD

The following healthcare professionals are authorised to administer

Hepatitis B Vaccines under the Patient Group Direction (NECSAT 2017/002)

PGD Valid from date: 1st March 2017 **PGD Expiry Date:** 31st March 2019

Healthcare Professional			**Authorised by:**		
Name	**Signature**	**Date**	**Name**	**Signature**	**Date**

PGD Valid from: 1st March 2017	Review Date: - Dec. 2018	**Expiry Date: - 31st March 2019**